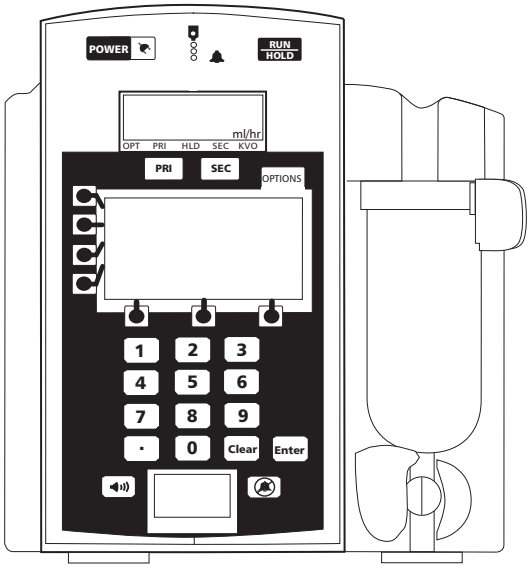
Directions for Use

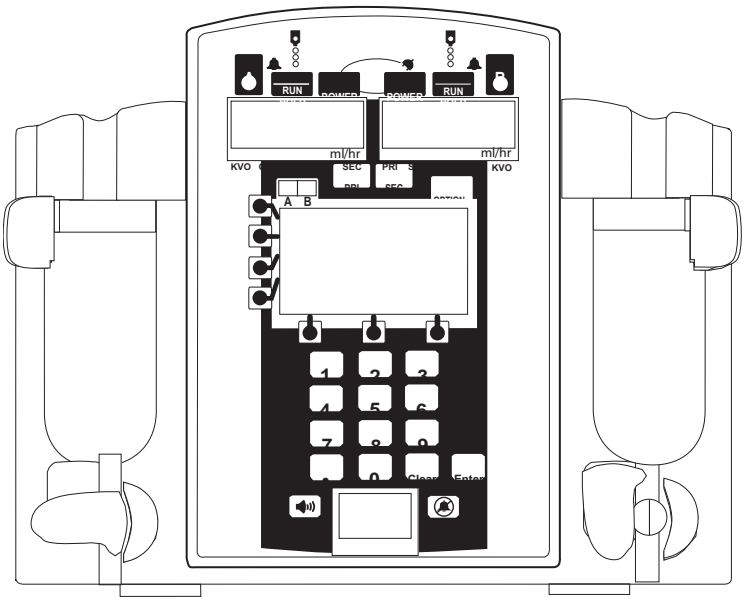
Alaris® SE Pump

Models 7130/7131 and 7230/7231

Supports Guardrails® Suite MX

June 2006





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Getting Started

Introduction

This document provides directions for use for the SE Pump, Models 7130/7131 and 7230/7231. It is used in conjunction with:

Alaris® product administration set instructions
Drug product labeling
SE Pump Technical Service Manual
Ground test equipment instructions
ECG monitoring system instructions

The SE Pump is intended for use in professional healthcare environments, including healthcare facilities, home care, and medical transport, that utilize infusion pumps for the delivery of fluids, medications, blood, and blood products. It is indicated for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, and irrigation of fluid spaces.

The SE Pump is available as either a single or a dual channel pump that supports the Guardrails® Suite MX. The SE Dual Channel Pump is a two-channel device intended to deliver multiple infusions to a single patient.

Guardrails® Suite MX for the SE Pump brings a new level of medication error prevention to the point of patient care. Guardrails® Suite MX features programming guidelines for medication dosing, delivery rate, duration, bolus dose and bolus dose administration rate, concentration and optional initial programming values in up to 15 patient-specific care areas referred to as profiles. Each profile contains a specific Drug Library and an IV Fluid library as well as instrument configurations appropriate for the care area. Optional drug-specific or fluid-specific clinical advisories provide visual messages. Limits for each Guardrails® drug or fluid entry may include Hard Limits that cannot be overridden during infusion programming and/or Soft Limits that can be overridden, based on clinical requirements.

A Data Set is developed and approved by the facility's own multi-disciplinary team using the Editor Software, the PC-based authoring tool. A Data Set is then transferred to the SE Pump by qualified personnel. Approved Data Sets are maintained by the Editor Software for future updates and reference.

WARNING

Read all instructions before using the SE Pump.

Introduction (Continued)

Information about a Guardrails® alert that occurs during use is stored within the SE Pump, and can be accessed using the CQI Reporter.

The SE Pump may be operated with or without the Guardrails® Suite MX protection. When an approved Data Set is transferred to the SE Pump by qualified personnel and the Profiles feature is enabled (ON) in instrument configuration, then Guardrails® Suite MX protection is available. When the Profiles feature is not enabled (Off), or when no Data Set has been transferred to the SE Pump, Guardrails® Suite MX protection is not available (see "Primary Infusion – NO Guardrails® Suite MX Protection", and "Secondary Infusion - NO Guardrails® Suite MX Protection"). Programming and navigation may differ when Guardrails® Suite MX software is not in use.

Documentation provided with this product may reference product not present in your facility or not yet available for sale in your area.

A superscript number (for example, ①) identifies additional information provided as a note at the end of the section.

Administration Sets: Reference “General Information” for specific “Administration Set Information”.

Alarms, Alerts, Prompts: Reference “Troubleshooting and Maintenance” for specific alarms, alerts and prompts.

Electromagnetic Environment: Reference “Regulations and Standards”, "Compliance”.

Contraindications: None known.

Warnings and Cautions:

Warnings and cautions provide information needed to safely and effectively use the SE Pump. Reference "General Information", "Warnings and Cautions".

A **◄ DANGER ►** is an alert to an imminent hazard which could result in serious personal injury and/or product damage if proper procedures are not followed.

A **WARNING** is an alert to a potential hazard which could result in serious personal injury and/or product damage if proper procedures are not followed.

Introduction (Continued)

Warnings and Cautions: (Continued)

A **CAUTION** is an alert to a potential hazard which could result in minor personal injury and/or product damage if proper procedures are not followed.

DEFINED TERMS:

The following table identifies the defined terms used throughout this document for certain products and product features.

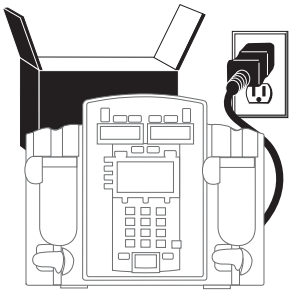
Product Name	Defined Term
AccuSlide® flow regulator	Flow Regulator
Alaris® SE pump	SE Pump
Guardrails® clinical advisory	Clinical Advisory
Guardrails® CQI Reporter	CQI Reporter
Guardrails® data set	Data Set
Guardrails® drug library	Drug Library
Guardrails® Editor	Editor Software
Guardrails® hard limit	Hard Limit
Guardrails® IV fluid	IV Fluid
Guardrails® soft limit	Soft Limit
SmartSite® needle-free valve	Needle-Free Valve
SmartSite® positive bolus needle-free valve	Needle-Free Valve

Unpacking

1. Remove instrument from carton.
2. **Important:** Plug instrument into an AC outlet a minimum of 24 hours prior to use.

   Maximum battery capacity, as well as gauge accuracy, is reached after several charge/discharge/recharge cycles, in the refresh process. Cardinal Health recommends that the battery be fully charged/discharged/recharged, using the refresh cycle, before placing the instrument in use.
3. Perform Periodic Inspections (reference "Troubleshooting and Maintenance", “Inspection Requirements”).

See "General Information", "Configurable Settings" for a list of the configurable features.



WARNING

Failure to **properly charge the battery** results in an instrument malfunction. Biomedical personnel in the facility are responsible for unpacking the instrument and ensuring the battery is fully charged before placing the instrument in use.

Check-In and Configuration

This is a quick reference procedure for check-in and configuration of new and recently serviced instruments.

WARNING

Instruments returned from the service depot may be set to factory defaults and not have a hospital-defined Data Set loaded. Biomedical personnel in the facility are responsible for checking-in the instrument and ensuring the current hospital-approved Data Set is loaded.

CAUTION

Charge the battery for a minimum of 24 hours prior to performing the check-in and configuration procedures. Batteries without a full charge on initial use may become damaged and/or cause a malfunction.

Rate Accuracy Qualification Test

This procedure is to be used only for the testing of an instrument during New Instrument Check-In or when just received from the Service Depot Center. This test is to verify that damage or changes to the instrument did not occur during shipment and handling.

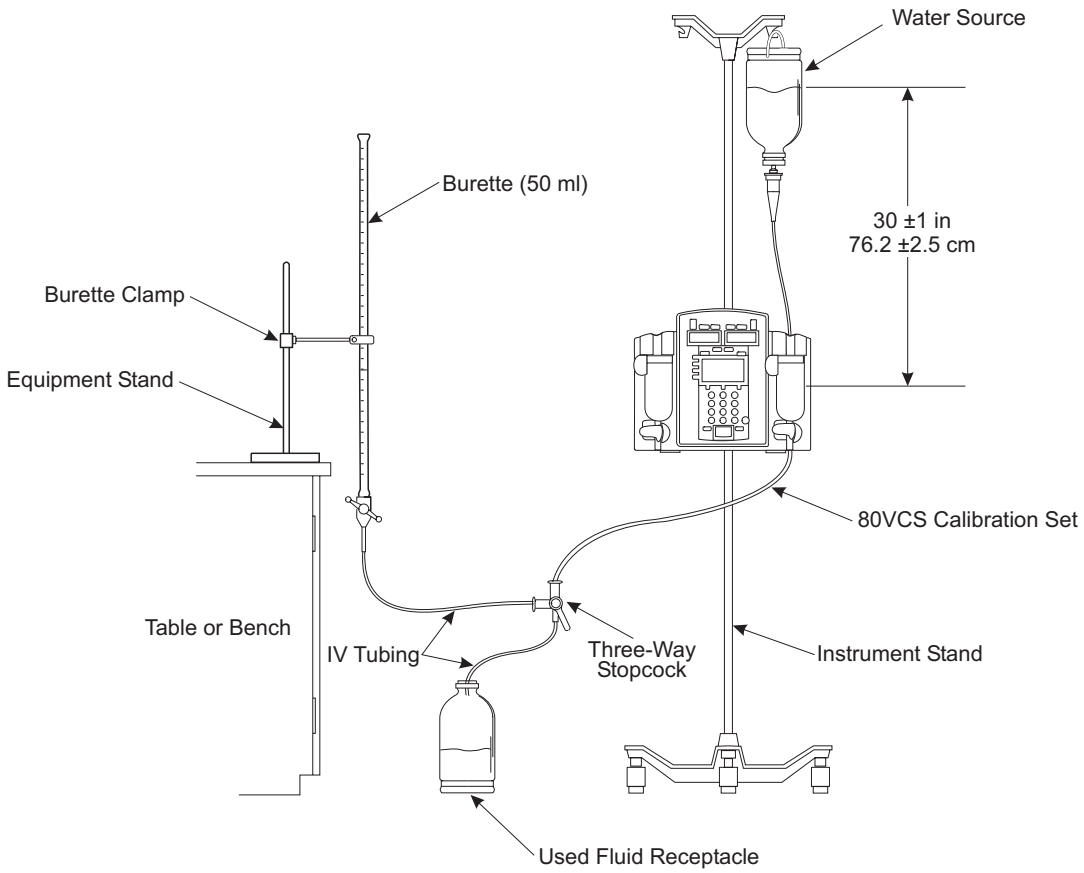
Rate accuracy should be tested using a Model 80VCS Calibration Set. The system is designed to produce overall accuracy of ±5% for rates greater than 1 mL/h and up to 999.9 mL/h, and ±6.5% for rates equal to or less than 1 mL/h, 95% of the time with 95% confidence (reference "General Information", "Trumpet and Start-Up Curves" for additional information). The system performance with a calibration set produces a smaller variability. In order to ensure overall accuracy is achieved, new instruments are tested to an accuracy of ±3% with the Model 80VCS set during New Instrument Check-In.

Due to the dynamic monitoring feature, the rate is varied during operation. For this reason, automatic testers should not be used to check rate accuracy. Generally, these devices collect small samples and may cause the results to be incorrect, even though the instrument is accurate.

Rate Accuracy Qualification Test (Continued)

Do not use the Model 80VCS Calibration Set for more than 30 rate verification runs (15 rate calibration number changes). Keep track of the number of times the set is used by recording each use on the 80VCS insert or on a separate record.

Test Setup



1. Fill solution container with clean tap water. Close Flow Regulator clamp on 80VCS set and then insert spike into solution container.
2. Open Flow Regulator clamp and prime set. Ensure all air is expelled from set. Close Flow Regulator clamp.
3. Connect output of set to one side of three-way stopcock.
4. Load set into instrument.

Rate Accuracy Qualification Test (Continued)

5. Close latch.
6. Verify no fluid flow or drops falling in drip chamber.
7. Plug instrument into a properly grounded AC outlet.
8. Set stopcock to output into a class A or B burette.
9. Press **POWER** key to turn channel on.
10. Set primary infusion rate to 400 mL/h.
11. Set VTBI to 20 mL.
12. Ensure instrument (both channels if dual channel) is set to **Pressure** mode. ①
13. Press **RUN/HOLD** key to start primary infusion. Infuse until tubing and burette are fully primed (approximately 1 minute).
14. Press **RUN/HOLD** key to stop infusion.
15. Adjust height of instrument and/or fluid container to attain a head height of 30 ±1 inches / 76.2 ±2.5 centimeters between middle of pumping mechanism and fluid level in: ②
    - bag or vented bottle (vent closed on administration set)

      OR
    - drip chamber (unvented bottle with vent open on administration set).
16. Adjust fluid level in burette until meniscus is level with zero mark on burette. ③
17. Verify primary infusion rate is 400 mL/h.
18. Reset VTBI to 40 mL and clear volume infused.
19. Press **RUN/HOLD** key to start primary infusion.
20. Instrument will run approximately 360 seconds (6 minutes) to complete delivery and then go into KVO mode. Stop instrument within 1 second of its entering KVO mode.
21. Make a note of volume collected in burette.
22. Note expected volume, as identified on 80VCS set insert.
23. Do not remove 80VCS set from instrument until one of following conclusions is determined:

Rate Accuracy Qualification Test (Continued)

- Instrument passes rate verification and calibration is not needed.
- Rate calibration number was changed and instrument now passes verification.
- Mechanism replacement is required.

24. Calculate volume accuracy, as follows:

    Volumetric Volume Accuracy Error Computation

    Vcollected = volume in burette in milliliters
    Vexpected = characterized volume printed on 80VCS set insert

    Step 1: A = **V**collected ÷ **V**expected
    Step 2: B = A x 100
    Step 3: % Error (round % Error to nearest tenth of a percent) = B – 100

25. Result should be 0.0±3%.

26. If volume accuracy does not fall within required range of ±3% from expected volume and test results were:
    - inside a range of -5.5% to +7.0% from expected volume,

      perform rate calibration (reference Technical Service Manual). Set rate calibration number to 0.0% before running rate test, to determine a new calibration number.
    - outside a range of -5.5% to +7.0% from expected volume,

      return instrument to Cardinal Health for repair or replace mechanism.

27. Set stopcock to drain fluid in burette to zero level, in preparation for next test.

NOTES:

① The factory default for the **Monitoring Options** mode is **Pressure**.

② A 30-inch head height was used in the initial qualification of this process and is the recommended head height for the Check-In Rate Accuracy Test. Based on observed field use, a 24-inch head height was also tested and verified for the Rate Accuracy Specification.

③ The instrument may need to be run to prime the line to the zero level of the burette (step 13).

Alternative Rate Accuracy Qualification Test

This procedure is to be used only for the testing of an instrument during New Instrument Check-In or when just received from the Service Depot Center. This test is to verify that damage or changes to the instrument did not occur during shipment and handling.

Make the following changes to Test Setup:

- Burette and equipment stand have been replaced by digital scale, Acculab Vic-212 or equivalent and 50 or 100 mL flask (plastic or glass).
- Three-way stopcock and used fluid receptacle are no longer needed.

Due to the dynamic monitoring feature, the rate is varied during operation. For this reason, Cardinal Health does not recommend using automatic testers to check rate accuracy. Generally, these devices collect small samples and may cause the results to be incorrect, even though the instrument is accurate.

Do not use the Model 80VCS set for more than 30 rate verification runs (15 rate calibration number changes). Keep track of the number of times the set is used by recording each use on the 80VCS insert or on a separate record.

1. Fill solution container with clean tap water. Close Flow Regulator clamp on 80VCS Calibration Set and then insert spike into solution container.
2. Open Flow Regulator clamp and prime set. Ensure all air is expelled from set. Close Flow Regulator clamp.
3. Place flask in middle of scale.
4. Load set into instrument.
5. Close latch.
6. Verify no fluid flow or drops falling in drip chamber.
7. Plug instrument into a properly grounded AC outlet.
8. Place output of set so it drips into flask. (Do not let set rest on flask.)
9. Press channel's **POWER** switch to turn channel on.
10. Set primary infusion rate to 400 mL/h.

Alternative Rate Accuracy Qualification Test (Continued)

11. Set VTBI to 20 mL.
12. Ensure instrument (both channels if dual channel) is set to **Pressure** mode. ①
13. Press **RUN/HOLD** key to start primary infusion. Infuse until tubing is fully primed (approximately 1 minute).
14. Press **RUN/HOLD** key to stop infusion.
15. Adjust height of instrument and/or fluid container to attain a head height of 30 ±1 inches between middle of pumping mechanism and fluid level in:
    - bag or vented bottle (vent closed on administration set)

      OR
    - drip chamber (unvented bottle with vent open on administration set).
16. Zero reading on scale.
17. Verify primary infusion rate is 400 mL/h.
18. Reset VTBI to 40 mL and clear volume infused.
19. Press **RUN/HOLD** key to start primary infusion.
20. Instrument will run approximately 360 seconds (6 minutes) to complete delivery and then go into KVO mode. Stop instrument within 1 second of entering KVO mode.
21. Make a note of scale reading in grams.
22. Note expected volume, as identified on 80VCS set insert.
23. Do not remove 80VCS set from instrument until one of following conclusions is determined:
    - Instrument passes rate verification and calibration is not needed.
    - Rate calibration number was changed and instrument now passes verification.
    - Mechanism replacement is required.

Alternative Rate Accuracy Qualification Test (Continued)

24. Calculate gravimetric accuracy as follows:

    Gravimetric Volume Accuracy Error Computation

    Vcollected = volume in flask in grams

    Vexpected = characterized volume printed on 80VCS set insert

    Step 1: A = Vcollected / Vexpected
    Step 2: B = A x 100
    Step 3: % Error (Round % Error to nearest tenth of a percent.) = B – 100

25. Result should be 0.0 ±3%.

26. If volume accuracy does not fall within required range of ±3.0% from expected volume and test results were:

    - inside a range of -5.5% to +7.0% from expected volume,

      perform rate calibration (reference Technical Service Manual). Set rate calibration number to 0.0% before running rate test, to determine a new calibration number.
    - outside a range of -5.5% to +7.0% from expected volume,

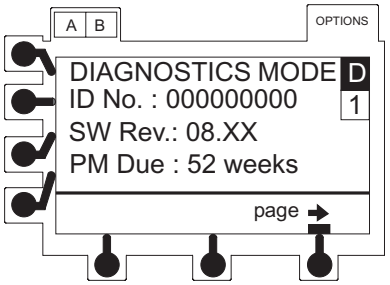
      return instrument to Cardinal Health for repair or replace mechanism.

27. Empty flask and reset scale to **zero**, in preparation for next test.

NOTE:

① The factory default for the **Monitoring Options** mode is **Pressure**.

Set Sensor Check / Pressure Calibration Verification



1. Access **DIAGNOSTICS MODE** by pressing and holding upper left soft key on power-up. Reference Technical Service Manual, "Troubleshooting" chapter, for details or contact Cardinal Health Technical Support. ①
2. Advance to **D6** page and choose **Cal Pressure** (both Channel A and Channel B for dual channel instruments).
3. Verify both **0 mmHg** and **500 mmHg** readings indicate Pass.
4. Install a standard set and close latch. Verify reading is over 170, to confirm set sensor operation.
5. Remove standard set and verify **Sensor =** reading is in -80 to +30 mmHg range without set installed, to verify pressure calibration. ②

NOTES:

① "08.XX" in the illustrated display represents the current software revision.

② If the reading is out of range, reference the Technical Service Manual, "Pressure Calibration" section, or contact Cardinal Health Technical Support for assistance.

Functional Test

1. Turn instrument on without set installed. Verify it beeps and red alarm light flashes but does not stay lit.
2. Set infusion rate to 460 mL/h and VTBI to 100 mL.
3. With latch closed, press **RUN/HOLD** key and rate and VTBI ≠ 0 to cause **Set Out** and **Air In Line** messages.
4. Open latch.
5. Install primed administration set with latch open.
6. Verify instrument displays **Air In Line** and **Latch Open** messages.
7. Close latch and verify display returns to setup page.

Functional Test (Continued)

8. Perform Upstream Occlusion Test, as follows:
   a. Verify infusion rate is set to 460 mL/h.
   b. With instrument on hold, or at start-up, verify primary VTBI is set to greater than 100 mL.
   c. Press **RUN/HOLD** key to begin infusion.
   d. Clamp off IV line just above instrument (about 2 inches) to simulate an upstream occlusion.
   e. Verify instrument stops running, alarms, and displays **OCCLUSION UPSTREAM** within 60 seconds.
   f. Press **RUN/HOLD** key to silence alarm and put instrument on hold.
   g. Release or open clamp and remove from tubing.
   h. Press **RUN/HOLD** key to resume infusion. Alarm should not reoccur.
9. Perform Downstream Occlusion Test, as follows:
   a. Continue infusing (from step 8h).
   b. Verify rate is set to 460 mL/h.
   c. Clamp off IV line just below instrument (about 2 inches) to simulate a downstream occlusion.
   d. Allow instrument to run until it alarms **OCCLUSION DOWNSTREAM**. Verify this occurs within 60 seconds.
   e. Press **RUN/HOLD** key to silence alarm and put instrument on hold.
   f. Release or open clamp and remove from tubing.
   g. Press **RUN/HOLD** key to resume infusion. Alarm should not reoccur.
   h. Press **RUN/HOLD** key to stop infusion.

Check-In and Configuration (Continued)

Flow Stop Test

1. With an administration set primed and loaded in instrument, turn power off.
2. With all tubing clamps open and fluid container 2 or more feet above instrument, verify no fluid flows through set.
3. Open latch and remove set. Verify no fluid flows through set.

Ground Current Leakage Test

Use a DNI Nevada Model 232D (or equivalent) to measure the ground leakage current. Refer to the test equipment's operation manual for the proper setup and measurement technique. Leakage current must be ≤100μA for normal and reversed line polarity.

Ground Resistance Test

Use a DNI Nevada Model 232D (or equivalent) to measure the ground resistance. Measure resistance from the AC power plug ground pin to the screw for the power cord strap, or to the screw for the battery cover on the chassis. Refer to the test equipment's operation manual for the proper setup and measurement technique. Resistance must be ≤0.10Ω.

CAUTION

Do not connect the ground resistance probe to the pressure transducer.

Instrument Configuration

Instrument Configuration for the SE Pump with the Guardrails® Suite MX is set for each profile using the Editor Software, the PC-based authoring tool. The Data Set is then transferred to the SE Pump by qualified personnel.

The SE Pump may be operated with or without the Guardrails® Suite MX protection. When an approved Data Set is transferred to the SE Pump by qualified personnel and the Profiles feature is enabled (ON) in instrument configuration, then Guardrails® Suite MX protection is available.

Instrument configuration is set by qualified personnel in the Data Set or Configuration and Diagnostics modes. When the Profiles feature is not enabled (Off), or when no Data Set has been transferred to the SE Pump, Guardrails® Suite MX protection is not available (see "Primary Infusion – NO Guardrails® Suite MX Protection" and "Secondary Infusion - NO Guardrails® Suite MX Protection").

Administration Set Information

General

The SE Pump uses a wide variety of Flow Regulator administration sets. The sets dedicated for use with the SE Pump are designed for use with the instruments as well as for gravity-flow stand-alone use. The unique, patented Flow Regulator has an integral flow control device that minimizes the risk of unintended flow when the set is removed from the instrument, and provides accurate rate control during gravity administration.

- For specific administration set instructions, reference directions for use provided with set.
- Use aseptic technique when handling sets and syringes.
- Administration sets are supplied with a sterile and non-pyrogenic fluid path for one time use. Do not re-sterilize or re-use.
- For administration set replacement interval, refer to facility protocol and/or government standards (such as: CDC guidelines in the United States) and see "SmartSite® Infusion Set" section of this Directions for Use (DFU).
- Discard administration set per facility protocol.
- For IV push medication (put instrument on hold), occlude tubing above injection port during administration.
- Flush port(s) per facility protocol.
- Place a sterile replacement cap on open end of tubing connector when not in use. Discard tubing when integrity has been compromised.

SmartSite® Infusion Set

The Needle-Free Valve is designed to permit injection and aspiration of fluids without the use of needles.

1. Use proper hand-hygiene procedures. Wash hands with conventional antiseptic-containing soap and water or disinfect with waterless alcohol-based gels or foams.
2. Prepare Needle-Free Valve.
    - Always swab top of valve port, **prior to every access**, with sterile 70% isopropyl alcohol wipe and allow to dry.①

-- Continued Next Page --

Administration Set Information (Continued)

SmartSite® Infusion Set (Continued)

- Replace every 72 hours or 100 activations, whichever comes first. ②

NOTES:

① For multiple syringes, swab prior to **each** syringe access.

② For infusions of blood, blood products or lipid emulsions replace every 24 hours.

Preparing Solution Container and Set

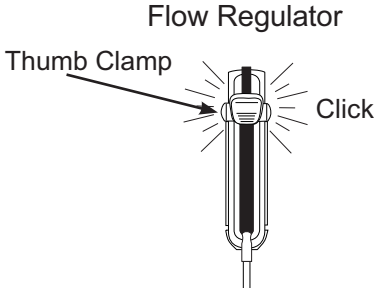
Prepare the primary solution container in accordance with the manufacturer's directions for use.

Use only sets dedicated for use with SE Pump.

WARNINGS

- Use only **sets dedicated** for use with the SE Pump. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard.
- **Discard if** packaging is not intact or protector caps are unattached.

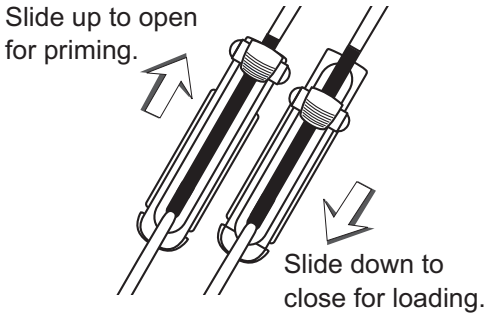
1. Slide Flow Regulator thumb clamp down until an audible click verifies it is in fully closed position.



2. Spike solution container.
3. Fill drip chamber to 2/3 full. ①
4. Invert Flow Regulator.

Preparing Solution Container and Set (Continued)

5. Slide Flow Regulator thumb clamp to open position to **slowly** prime set.
6. Close Flow Regulator clamp when priming is complete, as in Step 1. Verify no fluid is flowing.
7. A gravity flow rate may be adjusted with Flow Regulator thumb clamp, if desired.

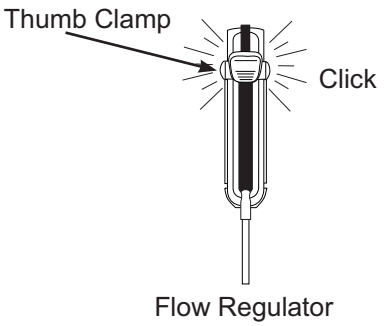


NOTE:

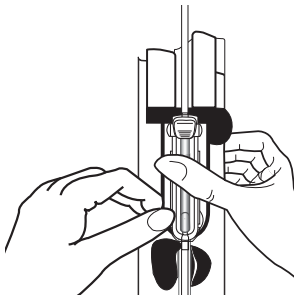
① Open the vent cap on the spike if the container requires venting.

Loading Set

1. Slide Flow Regulator thumb clamp down until an audible click verifies it is in fully closed position.



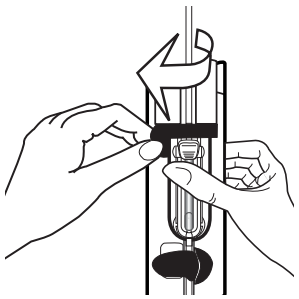
2. Using both hands, press top and bottom of Flow Regulator into instrument until it snaps into place.
   a. Verify 3 gray fingers (clamp arms) on each side of pumping mechanism have engaged Flow Regulator.
   b. Let go of set. A properly loaded set should stay in instrument.



Administration Set Information (Continued)

Loading Set (Continued)

3. Press firmly just below blue thumb clamp on Flow Regulator with one hand while using other hand to close latch fully to left.
   - If resistance is met while closing latch, remove set, verify Flow Regulator is fully closed and then reinstall set.
   - Verify thumb clamp has moved to open (up) position prior to starting infusion.



WARNING

After set installation, verify no fluid is flowing through the administration set's drip chamber, to avoid free-flow.

CAUTION

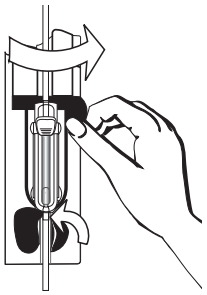
Before operating instrument, verify that administration set is **free from kinks and installed correctly** in instrument.

4. Attach set to patient's vascular access device.
5. Verify flow from IV container after starting infusion.

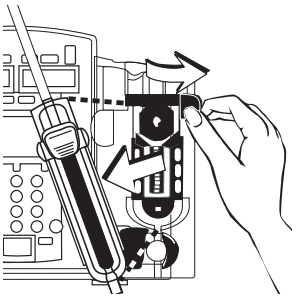
Administration Set Information (Continued)

Removing Set

1. Place channel on hold.
2. Open latch.
   - Flow Regulator automatically closes to prevent accidental unintended flow.



3. Press latch fully to right.
   - Set is ejected from instrument.



WARNING

Even though the instrument automatically closes the Flow Regulator, **verify the Flow Regulator is closed** when the set is removed from the instrument to prevent unintended flow.

CAUTION

Do not attempt to force the set from the instrument. Send the instrument to qualified service personnel.

Changing Solution Container

1. Place channel on hold.
2. Remove empty solution container.
3. Spike new container.
4. Ensure drip chamber is filled to 2/3 full.

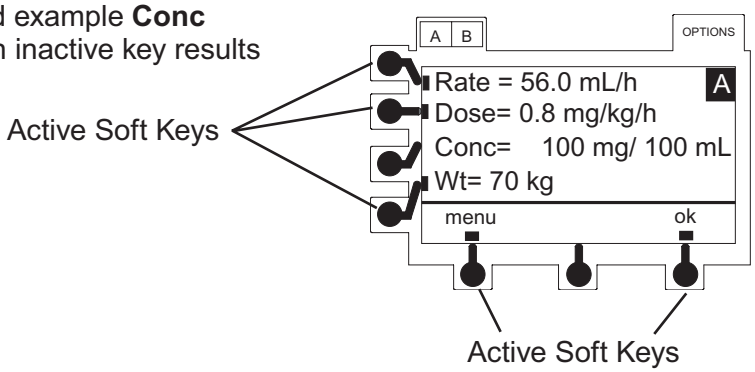
References throughout this procedure to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

Programming and Navigation Tips

Soft Keys

Soft Keys are the keys located on the left side and the bottom of the main LCD display. They serve a variety of functions, as indicated by the text in the display at the time. A soft key is active if there is a tick mark (**I**) next to the key.

If there is no tick mark next to the key, then it is not active and cannot be selected. [In the illustrated example **Conc** (concentration) is not active.] Pressing an inactive key results in an invalid keypress tone.



Entering Values

To enter programming values, select the desired parameter by pressing the corresponding soft key. The field is highlighted. To enter desired value, use the numeric keys then press the **ENTER** key.

A value must be highlighted to be changed.

A flashing highlight indicates that the entry is incomplete. Complete the entry and press the **ENTER** key.

To clear an existing value, press the **CLEAR** key. If the existing value should not be cleared, pressing the **CLEAR** key a second time (before pressing the **ENTER** key) restores that value.

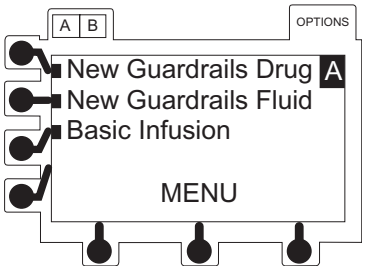
When all parameters required on a programming setup screen have been entered, the **ok** soft key is used to confirm all entries and continue programming.

Menus - With Guardrails® Suite MX Protection

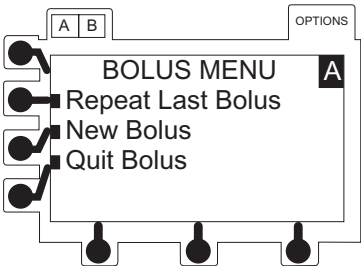
MENU screens provide access to the Profile drug libraries and to basic programming in both the primary and the secondary mode: ①

- MENU (Primary Main Menu)
- BOLUS MENU
- SECONDARY MENU

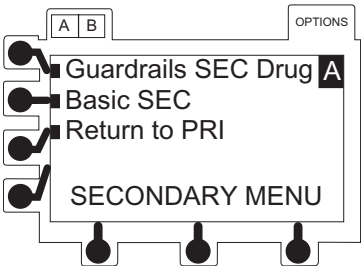
Press **menu** soft key while in primary programming mode to display MENU.



Press **menu** soft key while in bolus programming mode to display BOLUS MENU.



Press **menu** soft key while in secondary programming mode to display SECONDARY MENU.



NOTE:

① When the Profiles feature is not enabled (Off), or when no Data Set has been transferred to the SE Pump, Guardrails® Suite MX protection is not available and these menus do not appear.

Programming and Navigation Tips (Continued)

Menus - NO Guardrails® Suite MX Protection

MENU screens for optional modes can be accessed using the OPTIONS key:

- MULTI-STEP MENU
- MULTI-DOSE MENU
- DOSE RATE MENU

CAUTION

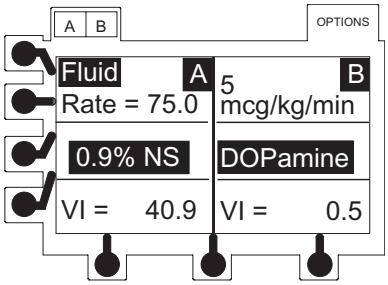
Guardrails® Suite MX protection is not available within the MULTI-STEP, MULTI-DOSE OR DOSE-RATE MENU options.

Split Screen (Dual Channel Only)

When both channels are infusing, a split screen showing programmed information for both channels displays automatically after one minute.

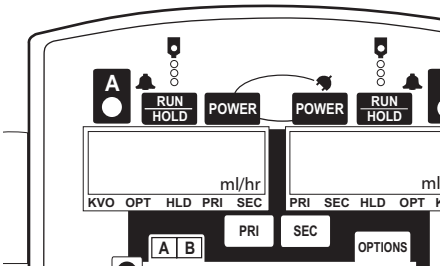
Press A B key to switch immediately to split screen.

Press A O or B O key to stop split screen.



Powering On and Off

1. To turn channel on, press channel's **POWER** key.
   - Instrument performs a self test when first channel is powered on.
   - All indicators and displays momentarily light.
   - An audio tone sounds.
   - Hold indicator flashes.



WARNING

Each time the instrument is turned on verify and/or set the monitoring mode, resistance alert and/or pressure alarm limit. If the monitoring mode, resistance alert and/or pressure alarm limit are not verified, the instrument may not be operating with the desired occlusion detection parameter(s).

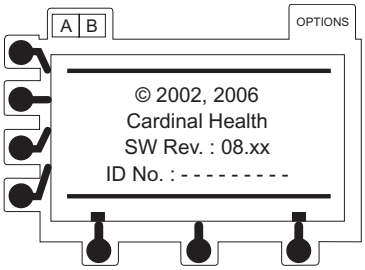
-- Continued Next Page --

Powering On and Off (Continued)

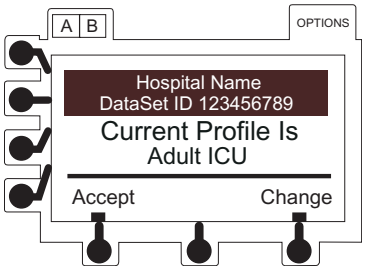
CAUTIONS

- **Appearance of lines and/or dots** that remain on constantly when the instrument is powered on may indicate improper functioning of the Main Display. Although the instrument is functioning, return it to qualified service personnel.
- Inspect LCD for anomalies (improperly lit/unlit pixels).

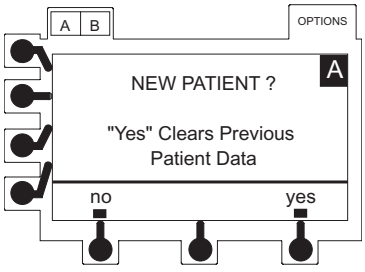
- System startup page displays briefly (08.XX in example display represents current software revision; ID No. is instrument serial number).



- When self test completes, if Guardrails® Suite MX protection is available, current profile screen appears.



- If Profiles feature is not enabled, then **NEW PATIENT?** screen appears.

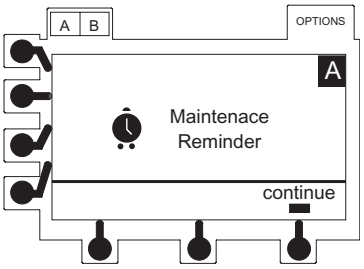


2. To power off, press and hold **POWER** key until display turns off.

Programming and Navigation Tips (Continued)

Responding to Maintenance Reminder

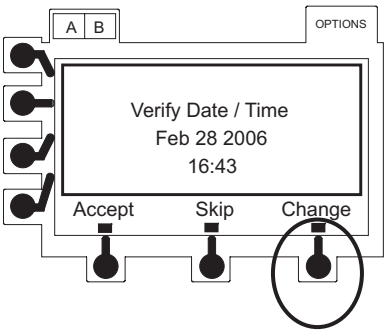
If the Preventive Maintenance Reminder option is enabled and the device is due for preventive maintenance a **Maintenance Reminder** message appears at power up.



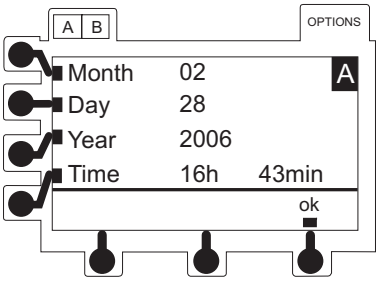
1. Notify appropriate facility personnel if a **Maintenance Reminder** message appears.
2. If necessary, press **continue** soft key to temporarily bypass reminder.

Responding to Time Set Reminder

Following certain battery depleted conditions it is necessary to re-set the internal clock so that CQI Reporter data integrity is maintained. In such cases, a Verify Time reminder message appears at power up.



1. Press **Change** soft key.
   - Time set screen displays.



2. Press soft key next to parameter to be changed.
   - Current value is highlighted.
3. To enter a new value, use numeric keypad, then press **ENTER** key.
4. Verify that all fields are correct then press **ok** soft key to continue programming.

Guardrails® Suite MX Prompts

Guardrails® Suite MX software allows the facility to create Soft and/or Hard Limits for Guardrails® continuous dose, Concentration, Guardrails® Bolus Dose, Bolus Dose Administration Rate, Guardrails® intermittent total dose, Intermittent Time, and IV Fluid Rate.

Within each profile the facility may also pre-define the following Hard Limits: maximum patient weight (kg), maximum patient body surface area (m^2) and maximum rate (mL/h).

Additional prompts are provided if Time or VTBI are edited resulting in a rate change, or if a VTBI significantly larger or smaller than the bag volume is entered.

Soft Limits

If programmed parameter is outside Soft Limit for that care area, a prompt appears before programming can continue.

1. If it is inappropriate to override Soft Limit, press **no** soft key.
   - Drug set up page displays.
2. Use numeric keys to enter a new value, then press **ENTER** key.

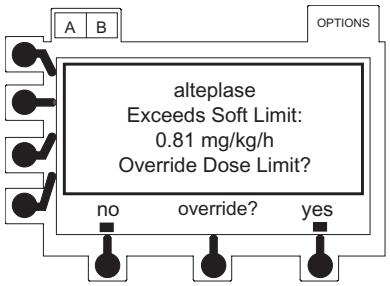
   OR
3. **If it is clinically appropriate and necessary** to override Soft Limit, press **yes** soft key.
   - Programming may continue.

When a maximum dose limit is exceeded, ↑↑↑ precedes the drug or fluid name. This indicates that the drug is infusing at a rate exceeding the defined maximum limit for that profile.

When a minimum dose limit is exceeded, ↓↓↓ precedes the drug or fluid name. This indicates that the drug is infusing at a rate less than the defined minimum limit for that profile.

WARNING

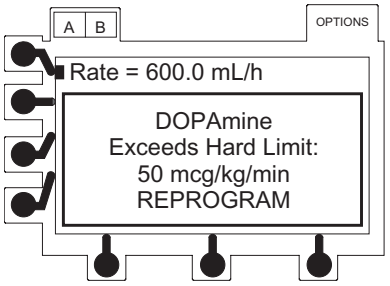
Prior to overriding a Soft Limit prompt, confirm the infusion parameters are correct.



Hard Limits

If programmed parameter is outside the Hard Limit for that care area, a prompt appears indicating a value within range must be entered before programming can continue.

Use numeric keys to enter a new value, then press **ENTER** key.



Selecting New Patient and Profile Options

Previous programming parameters may either be cleared or preserved.

Cleared, if:

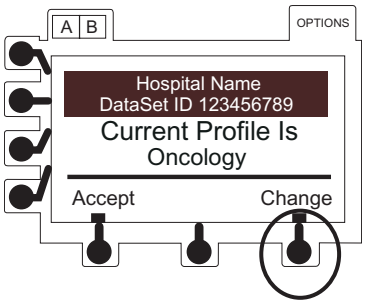
- Profile is changed.
- Profile is accepted but **New Patient? - yes** is selected.

Preserved, only if:

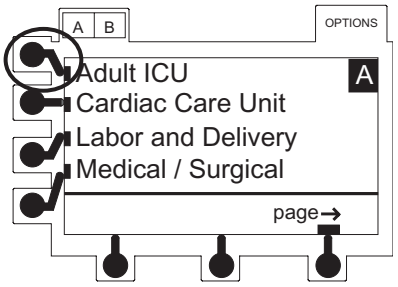
- Current Profile is accepted and **New Patient? - no** is selected.

Changing Profile

1. To change Profile, press **change** soft key.
   - Profile selection menu displays.



2. To view additional Profile selections, press **page** soft key.
3. Press soft key next to desired new Profile.
   - **Confirm Profile** screen appears.



CAUTION

If **the correct profile is not selected**, the instrument may not operate within the appropriate dosing limits and operating parameters.

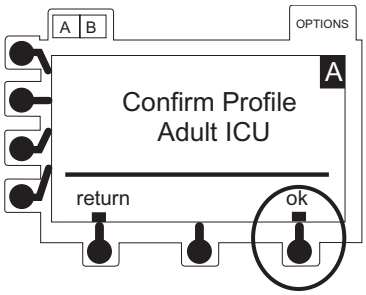
Selecting New Patient and Profile Options (Continued)

Changing Profile (Continued)

4. To confirm Profile selection, press **ok** soft key.

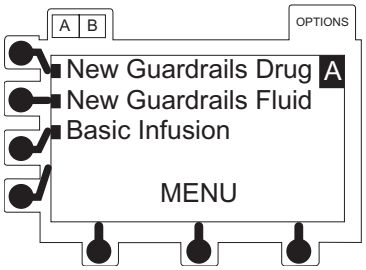
   OR

   To select another Profile, press **return** soft key.



Once confirmed:

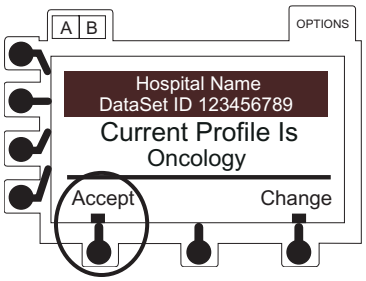
- Abbreviated Profile name appears in lower display.
- All previous programming parameters are cleared.
- MENU screen displays.



Accepting Profile

To retain currently active Profile, press **Accept** soft key.

- **NEW PATIENT?** screen displays.

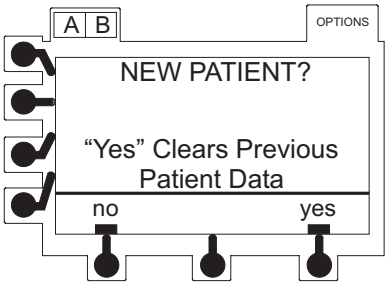


Selecting New Patient Option

To indicate programming is for a new patient and clear all stored patient parameters from memory, press **yes** soft key.

- All previous patient data clears and there is no option to **Resume Previous Drug** or **Resume Previous Fluid.**
- MENU screen displays.

OR



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Selecting New Patient and Profile Options (Continued)

Selecting New Patient Option (Continued)

To confirm programming is for same patient and retain all stored patient parameters, press **no** soft key.

- All previous patient data is maintained.
- MENU screen displays.
- If last infusion on that channel was a Drug Library entry, **Resume Previous Drug** appears as a MENU selection.
- If last infusion on that channel was an IV Fluid, **Resume Previous Fluid** appears as a MENU selection.
- If last infusion on that channel was an optional mode or a Basic Infusion, **Return to ….?** appears as a MENU selection.

Primary Infusion Introduction

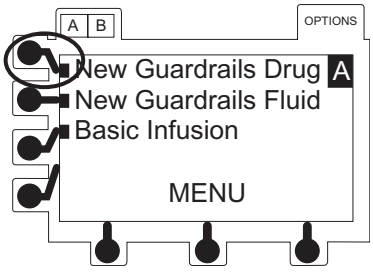
The following procedures are to be used only when the drug to be infused is listed in the Drug Library. To access the Drug Library, a hospital-defined best-practice Data Set must be transferred using the Editor Software and the Profiles feature must be enabled.

Continuous Infusion

When using a drug listed in the Drug Library, the drug parameters are automatically calculated based on:

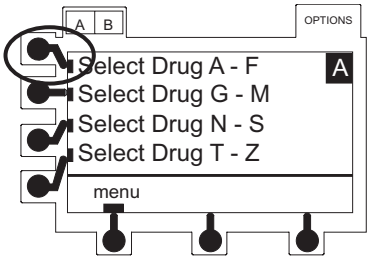
- drug and concentration selected
- weight entry (if required)
- rate or dose entry

1. Press **New Guardrails Drug** soft key.
   - If 15 or less drugs are available in selected profile, a list of drug names displays; otherwise, an alphabetic preselection menu displays.



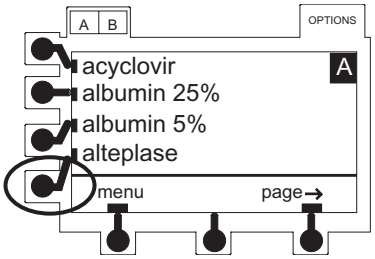
Continuous Infusion (Continued)

2. To use pre-selection menu press soft key corresponding to first letter of desired drug.

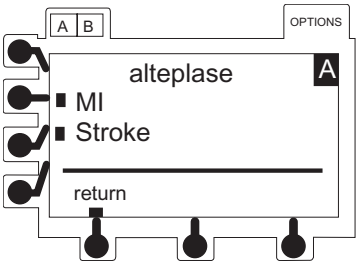


3. Press soft key next to desired drug name to select it.

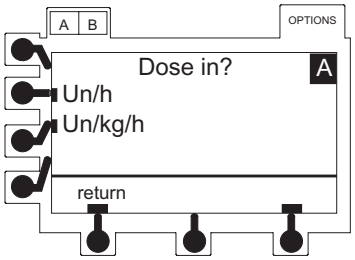
   - **page** soft key(s) may be used to view additional selections.



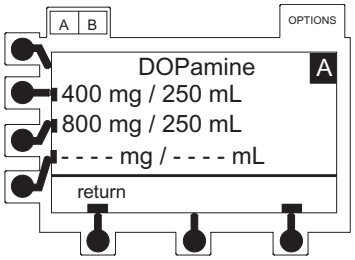
   - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion may appear (as in illustrated example, which reflects use of alteplase). Different limits can be defined for same drug with different therapeutic indications.



   - If applicable, a weight-based or non-weight-based option for delivery of this infusion may appear (as in illustrated example which reflects use of heparin).



   - If applicable, multiple concentration listings for delivery of this infusion may appear (as in illustrated example which reflects use of dopamine).

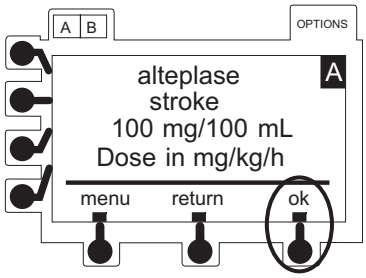


Continuous Infusion (Continued)

4. Press soft key next to desired selection.

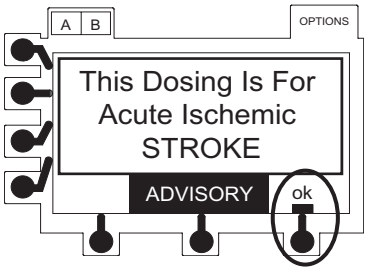
5. To confirm selection and continue programming, press **ok** soft key.

   - If a different selection is desired, press **return** soft key to return to the drug list or press **menu** soft key to return to MENU screen, then navigate to desired selection and press **ok** soft key.



6. If facility has defined a Clinical Advisory for selected drug, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.

   - Infusion setup page displays.

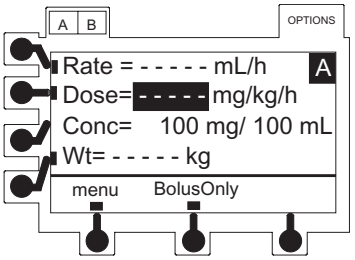


7. An optional hospital-defined and editable starting value for continuous infusion dose may already be entered.

   OR

   To enter a value, use numeric data entry keys then press **ENTER** key.

   - Dose field is highlighted for first entry, but soft keys can be used to highlight other parameters for entry prior to dose. To automatically calculate dose instead of rate, press **Rate** soft key and enter a rate value. Once all entries have been completed, dose is automatically calculated.
   - If a drug with a defined standard concentration was selected, **Conc** (concentration values, drug amount and diluent volume) are automatically entered. (Notice that these values are not editable).
   - If a drug with -- / -- mL was selected, **Conc** (concentration values of drug amount and diluent volume), needs to be entered.



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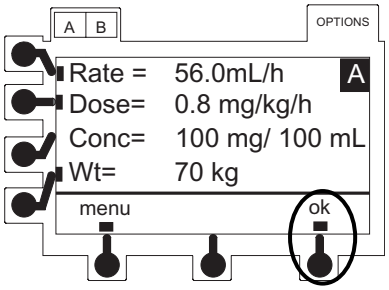
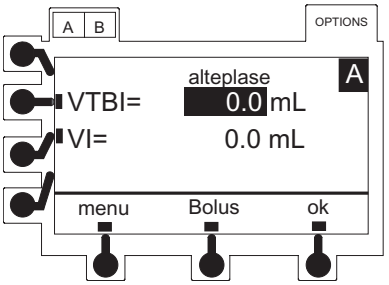
Continuous Infusion (Continued)

- If selected drug is weight-based, **Wt** (patient weight in kg) needs to be entered.
- If selected drug is not weight-based, **Wt** field does not appear.

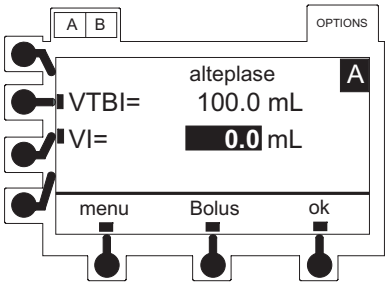
8. Verify that all parameters are correct and press **ok** soft key to confirm.



- VTBI and VI setup page displays.
- VTBI field is highlighted.



9. To enter desired VTBI, use numeric keys then press **ENTER** key.
   - VI field is highlighted.

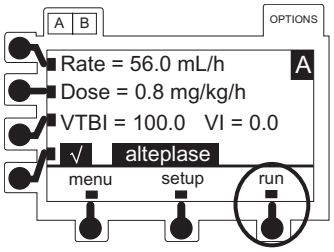


10. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.
11. To continue programming, press **ok** soft key.
    - RUN/HOLD page displays.

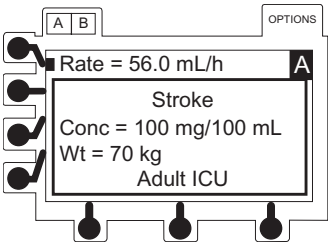
Primary Infusion - With Guardrails® Suite MX Protection (Continued)

Continuous Infusion (Continued)

12. Verify that all parameters are correct, then press **run** soft key or **RUN/HOLD** key to start infusion



13. To briefly view setup parameters (therapy, concentration, patient weight, current profile) from RUN/HOLD page or during a running infusion, press ✔ soft key.



Pausing and Restarting Infusion

1. An infusion may be paused temporarily by pressing channel **RUN/HOLD** key.
   - Rate LED flashes while infusion is on hold.
   - After 2 minutes, “Hold Time Exceeded” visual and audio prompts begin. An additional 2 minute period may be initiated by pressing either **hold** soft key or channel **RUN/HOLD** key.
2. To restart infusion while on hold, press channel **RUN/HOLD** key.

Making Changes During Continuous Infusion

Making Changes to Rate, Dose or VTBI

Continuous infusion parameters (Rate, Dose or VTBI) may be changed without pausing the infusion and VI may be cleared.

1. Select A/O or B/O key, as necessary.
2. Press soft key next to parameter to be edited.
   - Current value is highlighted.

Making Changes During Continuous Infusion (Continued)

Making Changes to Rate, Dose or VTBI (Continued)

3. Make changes:
   a. To enter a new value, use numeric keypad.
   b. To reset Volume Infused to 0.0 mL, press **CLEAR** or **0** (zero) key.
4. To accept new value, press **ENTER** key.

Making Changes to Concentration or Patient Weight

Infusion must be paused before making changes. If a drug with a defined standard concentration was selected, **Conc** (concentration) values are not editable.

1. To pause infusion, press channel's **RUN/HOLD** key.
2. Press **set up** soft key.
3. Press soft key next to parameter to be edited.
   - Current value is highlighted.
4. To enter a new value, use numeric keypad then press **ENTER** key.

Resuming Interrupted Infusion

If a channel has been powered off during an infusion, previous programming may be resumed if:

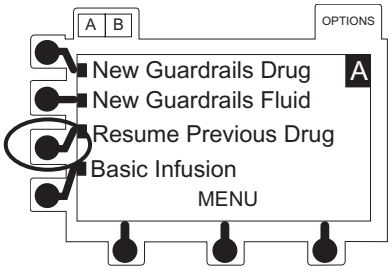
- One channel of a dual channel device remained on.
- Current profile is accepted and **New Patient? – no** is selected during start up (see "Selecting New Patient and Profile Options").

1. Select desired channel as necessary.

Primary Infusion - With Guardrails® Suite MX Protection (Continued)

Resuming Interrupted Infusion (Continued)

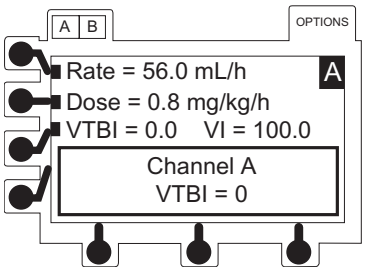
2. Press **Resume Previous Drug** soft key.
   - Previous drug review screen displays.



3. Press **ok** soft key to confirm drug, therapy, concentration and dosing units.
4. If facility has defined a Clinical Advisory for selected drug, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.
   - Previous infusion setup page appears.
5. Verify parameters are correct. If a change is required, see "Making Changes During Continuous Infusion".
6. Press **ok** soft key to continue.
   - RUN/HOLD page displays.
7. Verify that all parameters are correct, then press **run** soft key or **RUN/HOLD** key to start infusion.

KVO Mode

When the primary VTBI reaches 0.0mL, the instrument automatically switches to the configured KVO (keep vein open) rate, or remains at the current infusion rate, whichever is less.



- KVO rate flashes in rate LED display.
- Programmed infusion rate continues to display in Main Display.
- KVO flashes in infusion status bar.
- KVO alert tone sounds (may be silenced for 2 minutes using Silence key).
- VTBI = 0 (INFUSION IN KVO in Models 7131/7231) message flashes in Main Display.

Resuming Operation from KVO Mode

1. To place channel on hold, press **RUN/HOLD** key.
2. Press **VTBI** soft key.
   - VTBI is highlighted.
3. To enter desired VTBI, use numeric keys then press **ENTER** key.
4. To resume infusion, press **run** soft key or **RUN/HOLD** key.

Clearing Volume Infused

The volume infused counter increments as fluids are infused through a given channel. All fluids infused in primary mode, including boluses, all fluids infused in secondary mode and all fluids infused in KVO mode are counted.

1. To reset volume infused counter to 0.0mL, press **VI** soft key.
   - VI field is highlighted.
2. Press **CLEAR** key or press **0** (zero) key then press **ENTER** key.

Bolus Dose

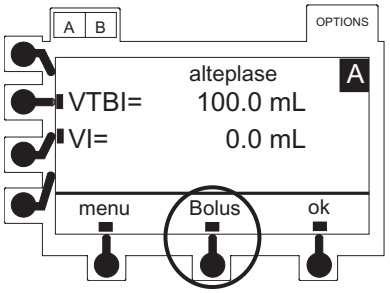
A Bolus Dose can be programmed at the beginning of, or during a continuous infusion. The drug being programmed must be a bolusable drug selected from the Drug Library, as described in the following procedures.

Bolus volume must be at least 1 mL and not more than 999.9 mL. Programming a bolus dose that calculates a bolus volume outside that range results in a message, "Bolus VTBI Less than 1 mL Not Allowed" or "Bolus VTBI More than 999.9 mL Not Allowed".

Bolus dose parameters may not be edited during bolus infusion. If new parameters are desired, select **New Bolus Dose** from the Bolus menu.

Delivering a Bolus Dose Prior to Beginning Continuous Infusion

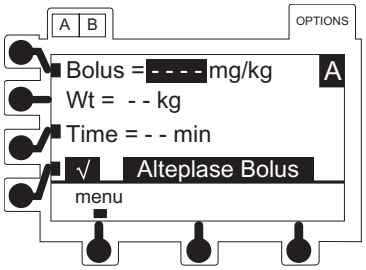
1. Set up infusion as described in “Continuous Infusion” procedure, steps 1 - 10. Do not start infusion.
2. On VTBI and VI setup page, press **Bolus** soft key.
   - **Bolus** programming page displays.
   - Bolus field is highlighted.



3. An optional hospital-defined and editable starting value for bolus dose may already be entered.

   OR

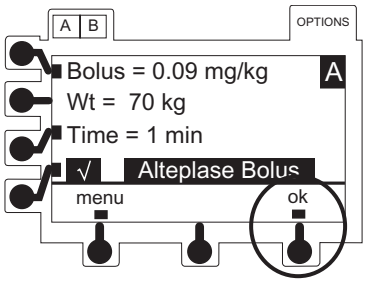
   To enter a value, use numeric data entry keys then press **ENTER** key.
   - If bolus is weight-based and weight has already been programmed in same channel, **Wt** (patient weight in kg) is automatically entered.
   - If bolus is weight-based and weight has not yet been programmed in same channel, **Wt** (patient weight in kg) needs to be entered.
   - If bolus is not weight-based, **Not Used** displays in **Wt** field.



4. An optional hospital-defined bolus dose administration rate may have been used to calculate an editable **Time** in minutes (1-99) to deliver programmed bolus dose.

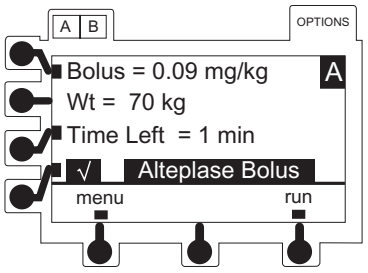
   OR

   To enter a **Time** value, use numeric data entry keys then press **ENTER** key.
5. Verify parameters are correct and press **ok** soft key (see "Guardrails® Suite MX Prompts").
   - Bolus RUN/HOLD page displays.



Delivering a Bolus Dose Prior to Beginning Continuous Infusion (Continued)

6. Verify that all parameters are correct, then press **run** soft key or **RUN/HOLD** key to start infusion.
   - When bolus dose completes, an audio tone sounds and “Bolus Dose Complete” briefly displays, and infusion automatically transitions to continuous rate.

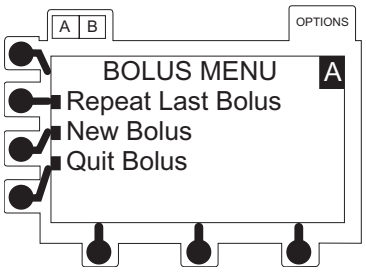


Delivering a Bolus Dose During a Continuous Infusion

1. Press **OPTIONS** key.
2. Press **Bolus** soft key.
   - BOLUS MENU displays.
3. Press **New Bolus** soft key.

   OR

   To repeat a previous bolus, press **Repeat Last Bolus** soft key.
   - Bolus Programming page displays.
   - Bolus field is highlighted.



4. An optional hospital-defined and editable starting value for bolus dose may already be entered.

   OR

   To enter a value, use numeric data entry keys then press **ENTER** key.
   - If bolus is weight-based and weight has already been programmed in same channel, **Wt** (patient weight in kg) is automatically entered.
   - If bolus is weight-based and weight has not yet been programmed in same channel, **Wt** (patient weight in kg) needs to be entered.
   - If bolus is not weight-based, **Not Used** displays in **Wt** field.

Delivering a Bolus Dose During a Continuous Infusion (Continued)

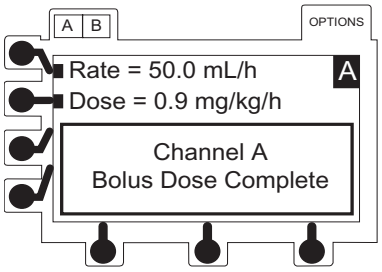
5. An optional hospital-defined bolus dose administration rate may have been used to calculate an editable **Time** in minutes to deliver programmed bolus dose.

   OR

   To enter a value, use numeric data entry keys then press **ENTER** key.

6. Verify parameters are correct and press **ok** soft key to transition from continuous to bolus infusion (see "Guardrails® Suite MX Prompts").

   - When bolus dose completes, an audio tone sounds and **Bolus Dose Complete** briefly displays, and infusion automatically transitions back to continuous rate.

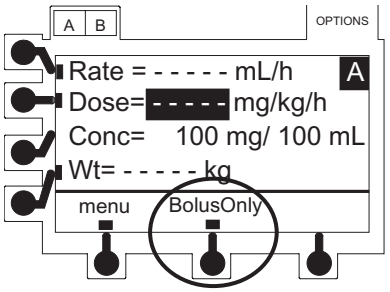


Bolus Only

The Bolus Only feature is used to deliver single boluses from a fluid container without delivering a continuous infusion. The feature is not available once a continuous dose or rate has been entered, or if an initial value for continuous infusion dose has been entered in the Data Set.

1. Follow steps 1 - 6 in "Continuous Infusion". DO NOT enter a dose or rate.
2. Press **BolusOnly** soft key.
   - Bolus Programming page displays.
   - Bolus field is highlighted.
3. An optional hospital-defined and editable starting value for bolus dose may already be entered.

   OR



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Bolus Only (Continued)

To enter a value, use numeric data entry keys then press **ENTER** key.

- If bolus is weight-based and weight has already been programmed in same channel, **Wt** (patient weight in kg) is automatically entered.
- If bolus is weight-based and weight has not yet been programmed in same channel, **Wt** (patient weight in kg) needs to be entered.
- If bolus is not weight-based, **Not Used** displays in **Wt** field.

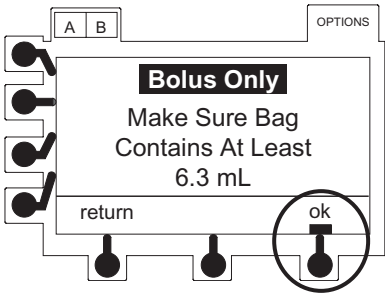
4. An optional hospital-defined bolus dose administration rate may have been used to calculate an editable **Time** in minutes (1-99) to deliver programmed bolus dose.

   OR

   To enter a time value, use numeric data entry keys then press **ENTER** key.

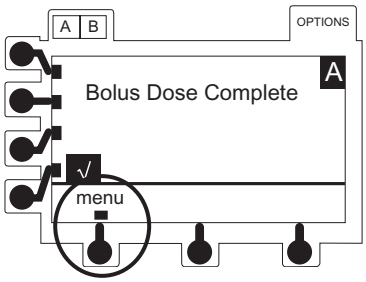
5. Verify parameters are correct and press ok soft key (see "Guardrails® Suite MX Prompts").
   - **Bolus Only** bag volume confirmation page displays.

6. Verify that bag contains an adequate volume to deliver programmed dose as specified and press **ok** soft key.
   - Bolus RUN/HOLD page displays.



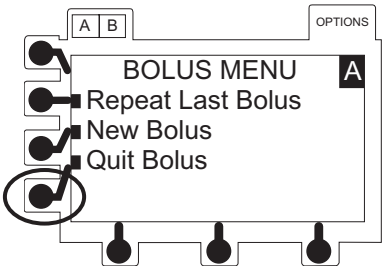
7. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
   - When bolus dose completes, an audio tone sounds and **Bolus Dose Complete** displays until user takes action.
   - No continuous infusion or KVO rate occurs.
   - Dashes "----" appear in Rate LED display.
   - No alarm occurs.

8. Press **menu** key to return to Bolus Menu.



Stopping Bolus Dose

1. To place channel on hold, press channel **RUN/HOLD** key.
2. Press **menu** soft key.
   - Bolus Menu displays.
3. Press **Quit Bolus** soft key.
4. To start continuous infusion, if one was programmed, verify parameters are correct and then press **run** soft key or channel **RUN/HOLD** key.



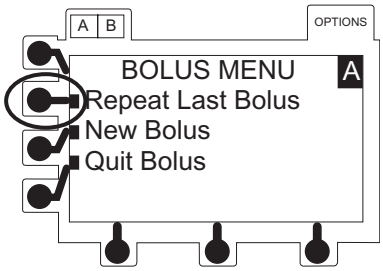
Repeating a Bolus Dose

A bolus dose that has completed may be repeated. If a bolus dose was stopped prior to completion the **Repeat Bolus Dose** soft key becomes inactive.

1. Press **Options** key.
2. Press **Bolus** soft key.
   - Bolus Menu displays.
3. Press **Repeat Last Bolus** soft key.
   - Bolus Programming page displays.
4. To accept current bolus dose and time values and begin bolus delivery, press **ok** soft key.

   OR

   To edit bolus or time, select desired field, use numeric data entry keys to enter a new value, then press **ENTER** key and press **ok** soft key to begin bolus delivery.
   - When bolus dose completes, an audio tone sounds, **Bolus Dose Complete** briefly displays, and infusion automatically transitions to continuous rate if one was programmed.
   - If no continuous rate or dose was programmed an audio tone sounds and **Bolus Dose Complete** displays until user takes action (see "Bolus Only").



Primary Infusion - With Guardrails® Suite MX Protection (Continued)

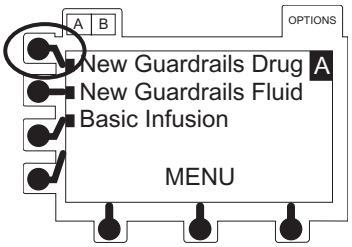
Intermittent Infusion

When using a drug listed in the Drug Library, the drug parameters are automatically calculated based on:

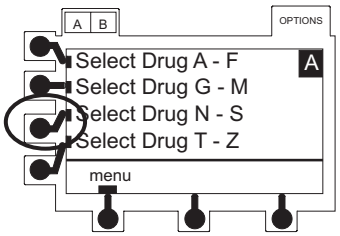
- drug amount
- weight entry or BSA entry (if required)
- VTBI entry
- time or rate entry

1. Press **New Guardrails Drug** soft key.

   - If 15 or less drugs are available in selected profile, a list of drug names displays; otherwise, an alphabetic pre-selection menu displays.

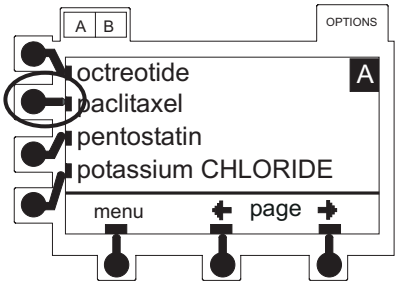


2. To use pre-selection menu press soft key corresponding to first letter of desired drug.

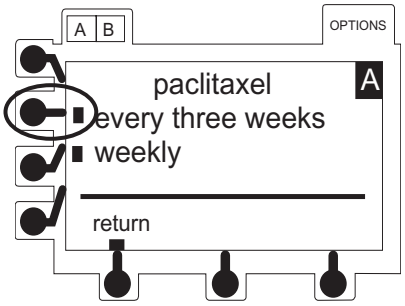


3. Press soft key next to desired drug name to select it.

   - **page** soft key(s) may be used to view additional selections.

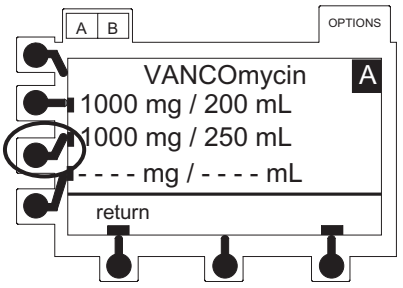


   - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion may appear (as in illustrated example, which reflects use of paclitaxel). Different limits can be defined for same drug with different therapeutic indications.



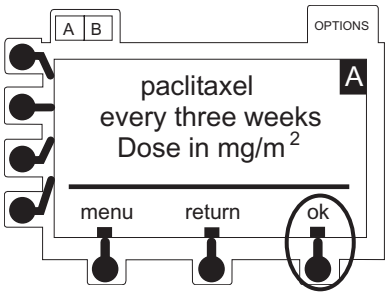
Intermittent Infusion (Continued)

- If applicable, a weight-based, non-weight-based or BSA-based option for delivery of this infusion may appear.
- If applicable, multiple concentration listings for delivery of this infusion may appear (as in illustrated example which reflects use of vancomycin).

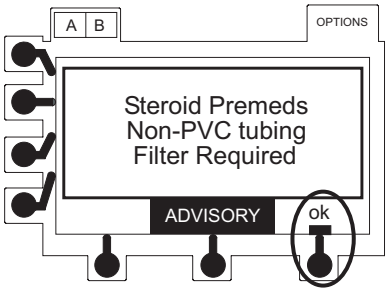


4. Press soft key next to desired selection.

5. To confirm selection and continue programming, press **ok** soft key.
   - If a different selection is desired, press **return** soft key to return to drug list or press **menu** soft key to return to MENU screen, then navigate to desired selection and press **ok** soft key.



6. If facility has defined a Clinical Advisory for selected drug, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.
   - Intermittent infusion setup page displays.

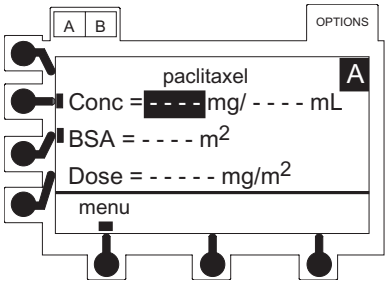


7. Enter parameters as needed.
   - If a drug with a defined standard concentration was selected, **Conc** (concentration values, drug amount and diluent volume) are automatically entered. (Note that these values are not editable).

-- Continued Next Page --

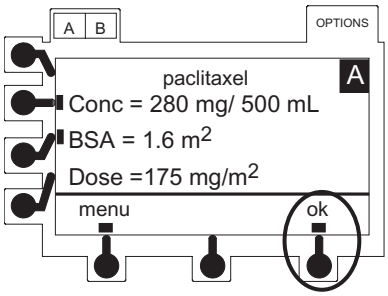
Intermittent Infusion (Continued)

- If a drug with -- / -- mL was selected, **Conc** (concentration values, drug amount and diluent volume), need to be entered. Drug amount is total dose of drug in fluid container. Diluent Volume is total volume of fluid container.

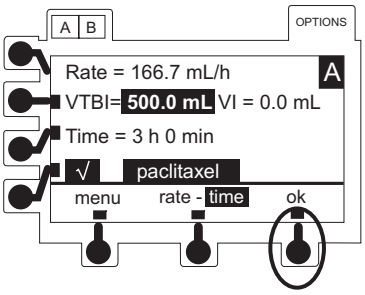


- If selected drug is weight-based, **Wt** (patient weight in kg) needs to be entered.
- If selected drug is BSA-based, **BSA** (body surface area in meters squared) needs to be entered.
- If selected drug is not weight-based or BSA-based, **Wt** or **BSA** field does not appear.
- Once all required parameters have been entered, total calculated dose displays. This value is not editable.

8. Verify that all parameters are correct and press **ok** soft key to confirm (see "Guardrails® Suite MX Prompts").



- Rate/VTBI/Time page displays.
- VTBI value is highlighted.
- An editable value derived from diluent volume is automatically entered.



9. To accept value, press **ENTER** key.

   OR

   To enter another value, use numeric data entry keys then press **ENTER** key.

   - The VI field is highlighted.

10. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.

Primary Infusion - With Guardrails® Suite MX Protection (Continued)

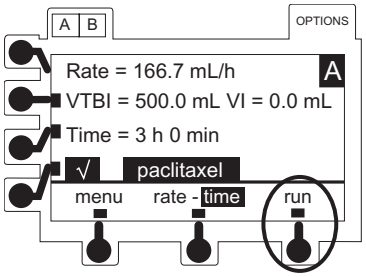
Intermittent Infusion (Continued)

11. An optional hospital-defined and editable starting value for time may already be entered.

    OR

    To enter a value, use numeric data entry keys to enter hours (0-99), then minutes (0-59). Press **ENTER** key to accept each entry.

    - Time can be entered to calculate rate or if rate entry is desired, press **rate - time** soft key. It changes to **rate - time**, indicating that rate may be entered.



12. Verify that all parameters are correct and press **ok** soft key (see "Guardrails® Suite MX Prompts").

    - RUN/HOLD page displays.

13. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.

14. To briefly view setup parameters (therapy, total dose, concentration, patient weight or BSA, current profile) from RUN/HOLD page or during a running infusion, press ✔ soft key.

Making Changes During Intermittent Infusion

Intermittent infusions must be paused to change parameters (Rate, VTBI or Time) or to clear VI.

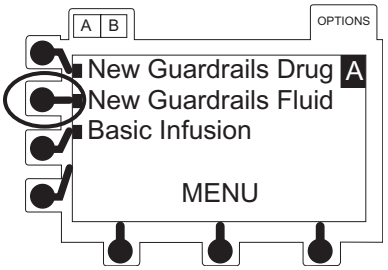
1. Press **RUN/HOLD** key for desired channel.
2. Press soft key next to parameter to be edited.
    - Current value is highlighted.
3. Make changes:
    a. To enter a new value, use numeric keypad.
    b. To reset volume infused to 0.0 mL, press **CLEAR** or **0** (zero) key.
4. To accept new value, press **ENTER** key.
    - Rate can be entered to calculate time or if time entry is desired, press **rate - time** soft key. It changes to **rate - time**, indicating that time may be entered.

Primary Infusion - With Guardrails® Suite MX Protection (Continued)

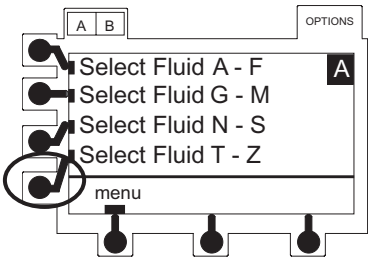
IV Fluid Infusion

1. Press **New Guardrails Fluid** soft key.

   - If 15 or less fluids are available in selected profile, a list of fluid names displays; otherwise, an alphabetic pre-selection menu displays.

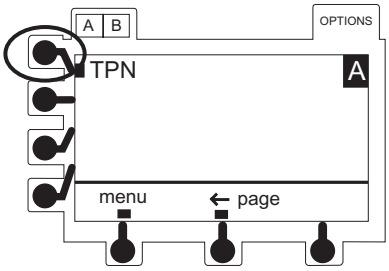


2. To use pre-selection menu press soft key corresponding to first letter of desired fluid.



3. Press soft key next to desired fluid name to select it.

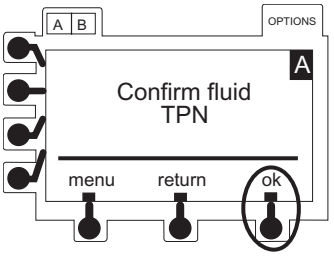
   - **page** soft key(s) may be used to view additional selections.
   - If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion may appear. Different rate limits can be defined for same fluid with different therapeutic indications.



4. Press soft key next to desired selection.

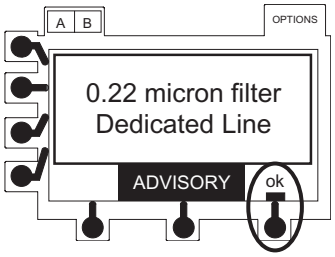
5. To confirm selection and continue programming, press **ok** soft key.

   - If a different selection is desired, press **return** soft key to return to fluid list or press **menu** soft key to return to **MENU** screen, then navigate to desired selection and press **ok** soft key.

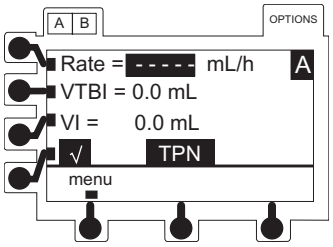


IV Fluid Infusion (Continued)

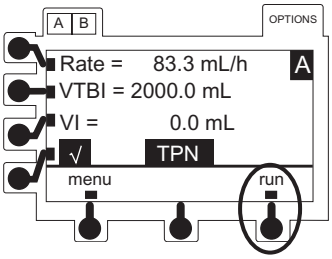
6. If a Clinical Advisory has been defined for selected fluid, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.



- IV Fluid setup page displays.
- Rate field is highlighted.



7. To enter a value, use numeric data entry keys then press **ENTER** key (see "Guardrails® Suite MX Prompts").
   - VTBI field is highlighted.
8. To enter a VTBI value, use numeric data entry keys then press **ENTER** key.
   - VI field is highlighted.
9. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.
10. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.



11. To briefly view current profile from RUN/HOLD page or during a running infusion, press ☑ soft key.

Secondary Infusion - With Guardrails® Suite MX Protection

Introduction

This mode is designed to support automatic secondary infusions (“piggybacking”) in the same channel. A secondary infusion can be programmed as a **Basic SEC** or **Guardrails SEC drug**. When the secondary VTBI reaches zero, an audio tone sounds (if enabled), **Secondary Complete** message displays briefly, and the primary infusion rate automatically resumes.

When the instrument is programmed and delivering in the secondary mode, the primary infusion is temporarily stopped and fluid is drawn from the secondary container. Delivery from the primary container resumes when the fluid level in the secondary line is level with the fluid in the primary container.

Primary infusion must be on hold to program secondary infusion.

A secondary infusion may be programmed only after a primary IV Fluid (that supports secondary mode) or a primary Basic Infusion has been programmed.

A list of IV Fluid entries is created in the Data Set that is developed and approved by the facility’s own multidisciplinary team using the Editor Software, the PC-based authoring tool. Each entry is determined to be either appropriate to support secondary infusions or not. The secondary key is unavailable for selections that have been designated as inappropriate for secondary delivery. Pressing the **SEC** key after programming a fluid that does not support secondary infusions results in a message, “Secondary not allowed with this fluid”.

The maximum rate for a secondary infusion is 600 mL/h. For information regarding flow sensor use with secondary infusions, see "General Information", "Flow Sensor".

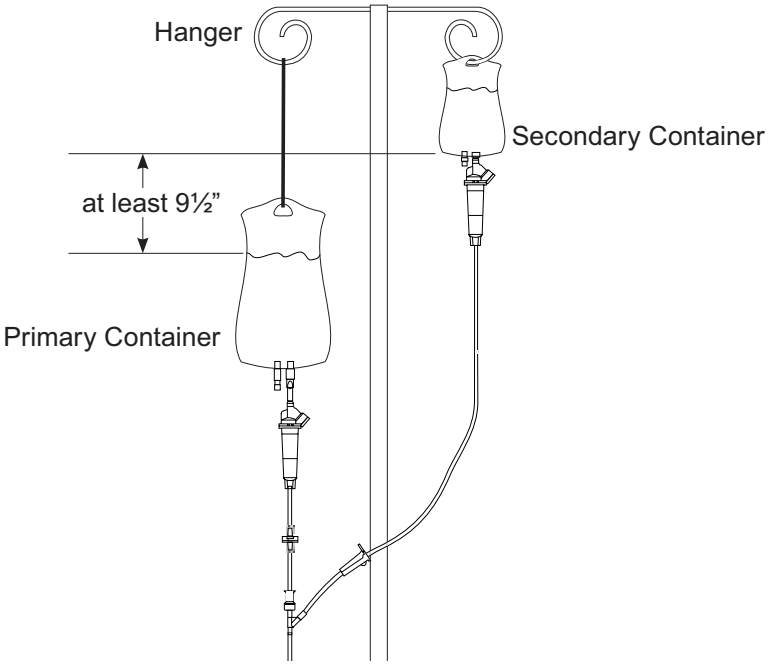
WARNINGS

- Secondary applications require the use of a **check valve set** on the primary IV line.
- The **secondary solution container** must be higher than the primary solution container.
- The **secondary VTBI settings** require consideration of variables; such as, factory overfill, medication additions. Underestimating the volume causes the remaining secondary solution to be infused at the primary rate; overestimating results in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.
- The clamp on the secondary administration set must be opened. If the **clamp is not opened**, the fluid is delivered from the primary container.
- The secondary administration set **must be primed** prior to beginning the secondary infusion.
- Ensure proper setup of secondary systems to make sure of proper flow.

Secondary Infusion - With Guardrails® Suite MX Protection (Continued)

Setup

1. Open secondary administration set package, remove set and close clamp.
2. Insert administration set spike into prepared fluid container and hang secondary container, following accepted hospital/facility procedure.
3. Fill drip chamber to 2/3 full.
4. Open secondary administration set clamp and prime set. Close clamp.
5. Attach secondary administration set to upper injection site on primary set.
6. Using hanger(s) provided with secondary administration sets, lower primary fluid container until bottom of secondary container is at least 9½” above fluid level in primary container.



Secondary Infusion - With Guardrails® Suite MX Protection (Continued)

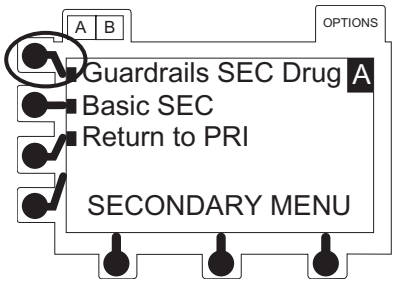
Secondary Intermittent Infusion

When using a secondary intermittent drug listed in the Drug Library, the drug parameters are automatically calculated based on:

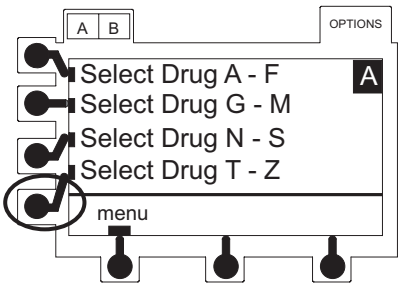
- drug amount
- weight entry or BSA entry (if required)
- VTBI entry
- time or rate entry

Primary infusion must be on hold to program secondary infusion.

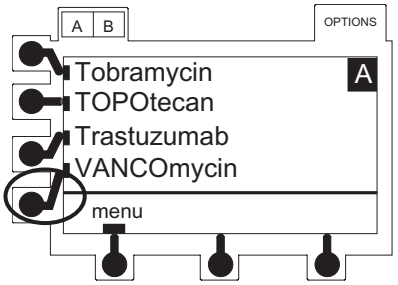
1. Press **SEC** key.
   - Secondary Menu displays.
2. Press **Guardrails SEC Drug** soft key.
   - If 15 or less drugs are available in secondary library of selected profile, a list of drug names displays; otherwise, an alphabetic pre-selection menu displays.



3. To use pre-selection menu press soft key corresponding to first letter of desired drug.



4. Press soft key next to desired drug name to select it.



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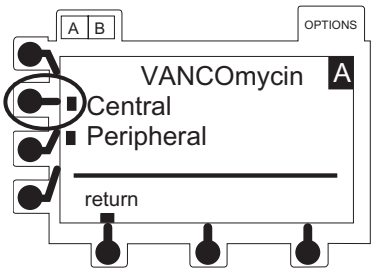
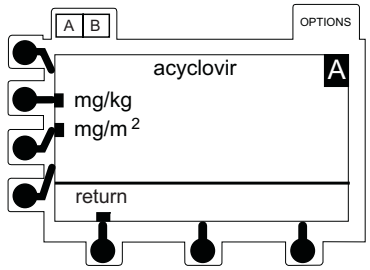
Secondary Infusion - With Guardrails® Suite MX Protection (Continued)

Secondary Intermittent Infusion (Continued)

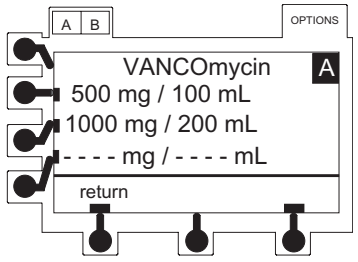
- If applicable, an optional hospital-defined therapy or clinical indication for delivery of this infusion may appear (as in illustrated example, which reflects use of vancomycin). Different limits can be defined for same drug with different therapeutic indications.



- If applicable, a weight-based, non-weight-based or BSA-based option for delivery of this infusion may appear (as in illustrated example, which reflects use of acyclovir).



- If applicable, multiple concentration listings for delivery of this infusion may appear (as in illustrated example which reflects use of vancomycin).



5. Press soft key next to desired selection.
6. To confirm selection and continue programming, press **ok** soft key.
   - If a different selection is desired, press **return** soft key to return to drug list or press **menu** soft key to return to **MENU** screen, then navigate to desired selection and press **ok** soft key.
7. If a Clinical Advisory has been defined for selected drug, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.
   - Intermittent infusion setup page displays.

Secondary Infusion - With Guardrails® Suite MX Protection (Continued)

Secondary Intermittent Infusion (Continued)

8. Enter parameters as needed.
   - If a drug with a defined standard concentration was selected, **Conc** (concentration values, drug amount and diluent volume) are automatically entered. (Note that these values are not editable).
   - If a drug with -- / -- mL was selected, **Conc** (concentration values, drug amount and diluent volume), needs to be entered. Drug amount is total dose of drug in fluid container. Diluent volume is total volume of fluid container.
   - If selected drug is weight-based, **Wt** (patient weight in kg) needs to be entered.
   - If selected drug is BSA-based, **BSA** (body surface area in meters squared) needs to be entered.
   - If selected drug is not weight-based or BSA-based, **Wt** or **BSA** field does not appear.
   - Once all required parameters have been entered, total calculated dose displays. This value is not editable.
9. Verify that all parameters are correct and press **ok** soft key to confirm (see "Guardrails® Suite MX Prompts").
   - Rate/VTBI/Time page displays.
   - VTBI field is highlighted.
   - An editable value derived from diluent volume is automatically entered.
10. To accept value, press **ENTER** key.

    OR

    To enter another value, use numeric data entry keys then press **ENTER** key.
    - VI field is highlighted.
11. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key. (This VI value includes all fluids infused on this channel in Primary and Secondary mode since last cleared.)

Secondary Infusion - With Guardrails® Suite MX Protection (Continued)

Secondary Intermittent Infusion (Continued)

12. An optional hospital-defined and editable starting time for Time may already be entered.

    OR

    To enter a value, use numeric data entry keys to enter hours (0-99), then minutes (0-59). Press **ENTER** key to accept each entry.

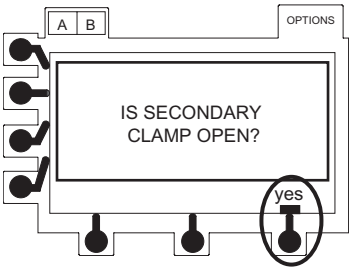
    - Time can be entered to calculate rate or if rate entry is desired, press **rate - time** soft key. It changes to **rate - time**, indicating that rate may be entered.

13. Verify that all parameters are correct and press **ok** soft key (see "Guardrails® Suite MX Prompts").

    - A Secondary Clamp reminder message displays.

14. Verify that secondary clamp is open before proceeding, then press **yes** soft key.

    - RUN/HOLD page displays.



15. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.

16. To briefly view setup parameters (therapy, total dose, concentration, patient weight or BSA and current profile) from RUN/HOLD page or during a running infusion, press ✔ soft key.

    - When secondary VTBI reaches 0.0mL:
      - An audio tone sounds (if enabled).
      - Channel _ Secondary Complete briefly displays.
      - Infusion automatically transitions to primary rate.

Primary Infusion - NO Guardrails® Suite MX Protection

The following procedures should be used only when the drug to be infused is not listed in the Drug Library or when the Profile feature is set to OFF in the instrument system configuration.

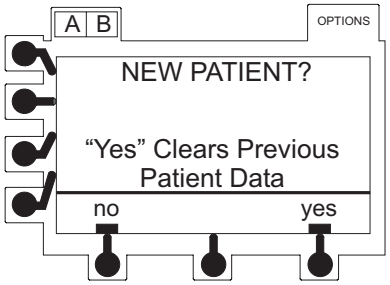
Selecting New Patient Option - Profiles Feature Not Enabled (OFF)

To indicate programming is for a new patient and clear all stored patient parameters from memory, press **yes** soft key.

- All previous patient data clears.

OR

To confirm programming is for same patient and retain all stored patient parameters, press **no** soft key.



Basic Infusion

If Guardrails® Suite MX protection is available and Basic Infusion is desired, it can be accessed through the MENU.

If the Profile feature is set to OFF in the instrument configuration, or no Data Set is loaded, the Basic Infusion page displays by default.

1. Press **Basic Infusion** soft key.
   - Basic Infusion RUN/HOLD page displays.
   - Rate field is highlighted.
2. To accept current value, press **ENTER** key.

   OR

   To enter desired value, use numeric data entry keys then press **ENTER** key.
   - VTBI field is highlighted.
3. To accept value, press **ENTER** key.

   OR

   To enter another VTBI value, use numeric data entry keys then press **ENTER** key.
   - VI field is highlighted.

Primary Infusion - NO Guardrails® Suite MX Protection (Continued)

Basic Infusion (Continued)

4. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.

5. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.

6. To briefly view current profile from RUN/HOLD page or during a running infusion, press ✔ soft key.

Promoting Basic Infusion to Guardrails® Suite MX Protection Infusion

When the Profiles feature is set to OFF or when no Data Set has been transferred to the SE Pump, Guardrails® Suite MX protection is not available and this section does not apply.

A basic infusion may be promoted to a continuous drug infusion or a fluid infusion with Guardrails® Suite MX protection while infusing.

A basic infusion may not be promoted to an intermittent drug. If an intermittent drug is selected a **Pri Running** message is displayed.

Promoting Basic Infusion to Guardrails® Drug Infusion

Infusion must be running in the Basic Primary Mode.

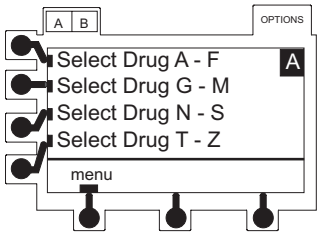
1. Select desired channel as necessary.

2. Press **Options** key.

3. Press **Guardrails Menu** soft key.

4. Press **New Guardrails Drug** soft key.

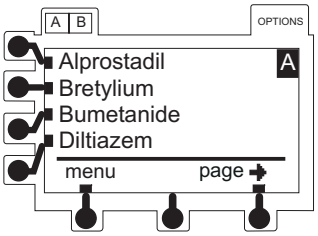
5. To use pre-selection menu press soft key corresponding to first letter of desired drug.



Promoting Basic Infusion to Guardrails® Drug Infusion (Continued)

6. Press soft key next to desired drug name to select it.

   - **page** soft key(s) may be used to view additional selections.



7. To confirm selection and continue programming, press **ok** soft key.

   - If a different selection is desired, press **return** soft key to return to drug list or press **menu** soft key to return to MENU screen, then navigate to desired selection and press **ok** soft key.

8. If a Clinical Advisory has been defined for selected drug, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.

   - Dose field is highlighted.

9. An optional hospital-defined and editable starting value for continuous infusion dose may already be entered.

   OR

   To enter a value, use numeric data entry keys then press **ENTER** key.

   - Dose field is highlighted for first entry, but soft keys can be used to highlight other parameters for entry prior to dose. To automatically calculate dose instead of rate, press **rate** soft key and enter a rate value. Once all entries have been completed, dose is automatically calculated.
   - If a drug with a defined standard concentration was selected, **Conc** (concentration values, drug amount and diluent volume) is automatically entered. (Note that these values are not editable).
   - If a drug with -- / -- mL was selected, **Conc** (concentration values, drug amount and diluent volume), needs to be entered.

-- Continued Next Page --

Promoting Basic Infusion to Guardrails® Drug Infusion (Continued)

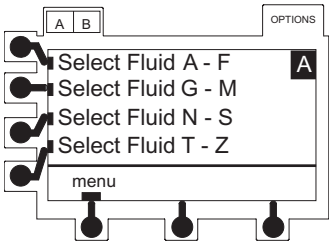
- If selected drug is weight-based, **Wt** (patient weight in kg) needs to be entered.
- If selected drug is not weight-based, **Wt** (patient weight) field does not appear.

10. Verify that all parameters are correct and press **ok** soft key to confirm.

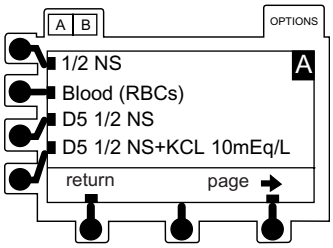
Promoting Basic Infusion to Guardrails® IV Fluid Infusion

Infusion must be running in the Basic Primary Mode.

1. Select desired channel as necessary.
2. Press **Options** key.
3. Press **Guardrails Menu** soft key.
4. Press **New Guardrails Fluid** soft key.
5. To use pre-selection menu press soft key corresponding to first letter of desired fluid.



6. Press soft key next to desired fluid name to select it.
   - **page** soft key(s) may be used to view additional selections.



7. To confirm selection and continue programming, press **ok** soft key.
   - If a different selection is desired, press **return** soft key to return to fluid list or press **menu** soft key to return to MENU screen, then navigate to desired selection and press **ok** soft key.

Promoting Basic Infusion to Guardrails® IV Fluid Infusion (Continued)

8. If a Clinical Advisory has been defined for selected fluid, a message appears. To indicate that information has been noted and continue programming, press **ok** soft key.
   - IV Fluid setup page displays.
   - Rate field is highlighted and flashing indicating that current value must be either approved or edited.
9. To accept current rate press **ENTER** key.

   OR

   To enter a value, use numeric data entry keys then press **ENTER** key.

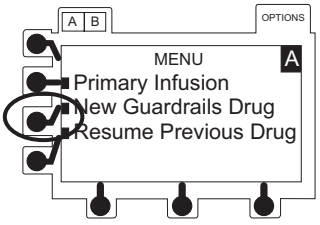
Dose Rate Calculation-Drug? NO DOSE LIMIT - Profiles Feature Enabled (ON)

The following procedures are to be used only when the drug to be infused is NOT listed in the Drug Library.

When using **Drug? – NO DOSE LIMIT**, drug parameters are automatically calculated based on:

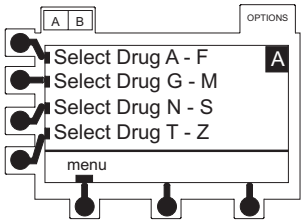
- concentration
- weight entry (if required)
- rate or dose entry

1. Press **New Guardrails Drug** soft key.
   - If 15 or less drugs are available in selected profile, a list of drug names displays; otherwise, an alphabetic pre-selection menu displays.



2. To use pre-selection menu press T – Z soft key, press **page** soft key to go to end of drug list, then press **Drug? – NO DOSE LIMIT** soft key.

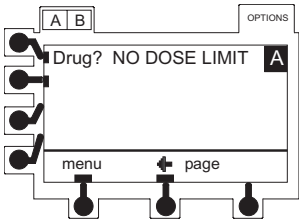
   OR



-- Continued Next Page --

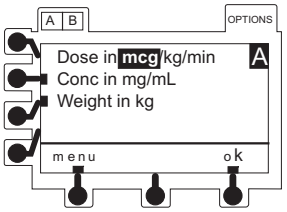
Dose Rate Calculation-Drug? NO DOSE LIMIT - Profiles Feature Enabled (ON) (Continued)

Press **0** (zero) numeric key then press **Drug? – NO DOSE LIMIT** soft key.



- Dosing unit in dose/weight/time displays with dose segment highlighted.

3. To scroll through units available, press and release soft key. When correct unit is displayed, press **ENTER** key.



   - If weight-based dosing is desired, press **ENTER** to advance to time segment

     OR

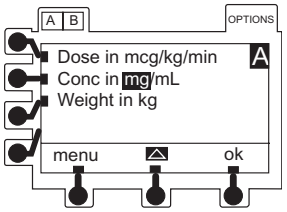
     If non-weight-based dosing is desired, press soft key to clear segment, then press **ENTER** (weight field disappears).
   - If time unit is appropriate, press **ENTER** to advance to concentration field.

     OR

     Press soft key to scroll through available time unit choices. Press **ENTER** when correct unit displays.
   - If concentration unit is appropriate, press **ENTER** to advance.

     OR

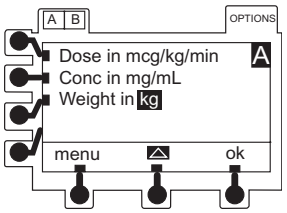
     Press soft key to scroll through available concentration unit choices. Press **ENTER** when correct unit displays.



   - If weight field appears and weight entry in kg (kilograms) is desired, press **ok** soft key to advance to programming page.

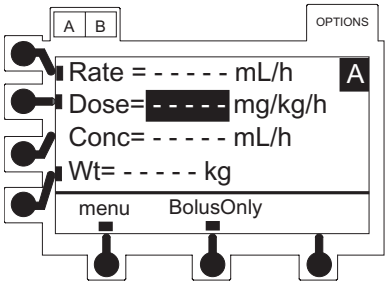
     OR

     If weight entry in lb (pounds) is desired, press soft then press **ENTER**. Press **ok** soft key to advance to programming page. Patient weight in pounds is used to automatically calculate dose per kilogram per time.



Primary Infusion - NO Guardrails® Suite MX Protection (Continued)

Dose Rate Calculation-Drug? NO DOSE LIMIT - Profiles Feature Enabled (ON) (Continued)



4. Enter parameters as needed.
   - Dose field is highlighted for first entry but soft keys can be used to highlight other parameters for entry prior to dose. To automatically calculate dose instead of rate, press **rate** soft key and enter a rate value. Once all entries have been completed dose is automatically calculated.
5. Verify that all parameters are correct and press **ok** soft key to confirm.
   - VTBI and VI setup page displays.
   - VTBI field is highlighted.
6. To enter a VTBI value, use numeric data entry keys then press **ENTER** key.
   - VI field is highlighted.
7. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.
8. To continue programming, press **ok** soft key.
   - RUN/HOLD page displays.
9. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
10. To briefly view current setup parameters (concentration, patient weight, current profile) from RUN/HOLD page or during a running infusion, press ☑ soft key.

Dose Rate Calculation-Profiles Feature Not Enabled (OFF)

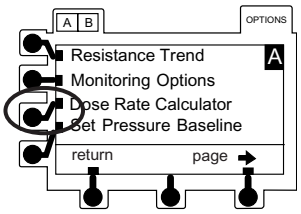
This feature allows the clinician to select a drug name from a pre-set list or to select a generic calculation feature by selecting “Drug?” to calculate drug parameters for drugs not on the list. If the preset list is disabled in the instrument configuration settings, then only generic calculation is available. Parameters are calculated automatically based on:

- concentration
- weight entry (if required)
- rate or dose entry

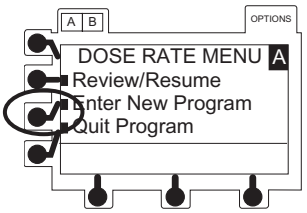
Primary Infusion - NO Guardrails® Suite MX Protection (Continued)

Dose Rate Calculation-Profiles Feature Not Enabled (OFF) (Continued)

1. Press **OPTIONS** soft key.
   - Options page appears.
2. Press **Dose Rate Calculator** soft key.



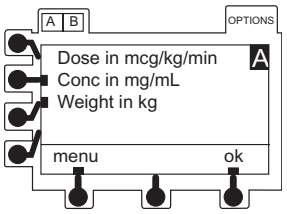
3. Press **Enter New Program** soft key.
   - An alphabetic pre-selection menu is displayed.



4. To use pre-selection menu press soft key corresponding to first letter of desired drug.
5. Press soft key next to desired drug name to select it.
   - **page** soft key(s) may be used to view additional selections.
   - If desired drug name is not listed, see “Drug? NO DOSE LIMIT-Profiles Feature Enabled (On)”.
6. To approve all displayed information and advance to setup page press **ok** soft key

   OR

   To change concentration or weight units press soft key next to parameter to be changed.
   - soft key appears.
   - To scroll through available selections, press soft key. When desired unit displays, press **ENTER** key, then press **ok** soft key to continue programming.



7. Press **ok** soft key to confirm selection and dosing units.
   - Infusion setup page displays.

Dose Rate Calculation-Drug? NO DOSE LIMIT - Profiles Feature Not Enabled (OFF) (Continued)

8. To enter desired values, use numeric keys then press **ENTER** key.
   - Dose field is highlighted for first entry, but soft keys can be used to highlight other parameters for entry prior to dose. To automatically calculate dose instead of rate, press **Rate** soft key and enter a rate value. Once all entries have been competed, dose is automatically calculated.
   - **Conc** (concentration values of drug amount and diluent volume) needs to be entered.
   - If drug is weight-based, **Wt** (patient weight) needs to be entered.
   - If drug is not weight-based, **Wt** field does not appear.
9. When all fields have been completed, verify that all parameters are correct and press **ok** soft key to confirm
   - VTBI and VI setup page displays.
   - VTBI field is highlighted.
10. To enter a VTBI value, use numeric data entry keys then press **ENTER** key.
    - VI field is highlighted.
11. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.
12. To continue programming, press **ok** soft key.
    - RUN/HOLD page displays.
13. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
14. To briefly view current dose rate setup parameters (concentration, patient weight) from RUN/HOLD page or during a running infusion, press ☑ soft key.

Loading Dose

This feature allows an initial infusion rate to be set up for a specific volume, automatically followed by a maintenance rate (primary settings) from the same container. If delivering a bolus dose of medication to load prior to the start of a continuous infusion, see "Primary Infusion - With Guardrails® Suite MX Protection", "Bolus Dose". The primary VTBI and VI include the loading dose volumes. When the loading dose VTBI reaches zero, a transition tone sounds (if transition tone feature is enabled), **Load Dose Complete** message displays briefly, and the primary settings automatically take effect.

Verify the primary mode parameters prior to accessing the **Loading Dose** option.

WARNING

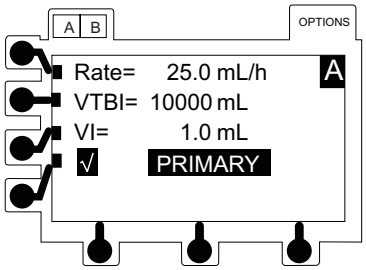
This mode is useful for delivering fluid challenges. This feature is for delivery from primary containers only. **Using this feature with 2 separate containers** may result in unintended flow rates.

CAUTION

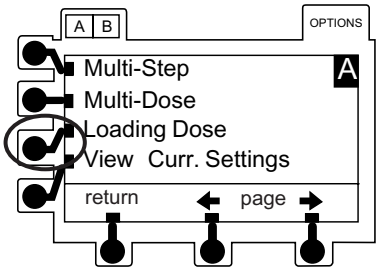
Guardrails® drug dosing limits are available only within the **New Guardrails Drug** or **New Guardrails IV Fluids** option. Dosing limits do not apply when using Loading Dose programming. Profile configurable options, as defined in the Data Set, do apply.

Programming

1. Select desired channel, as necessary. Channel must be on hold in primary mode.



2. Press **OPTIONS** key.
3. Press **Loading Dose** soft key.
   - Loading Dose infusion rate is highlighted.



Loading Dose (Continued)

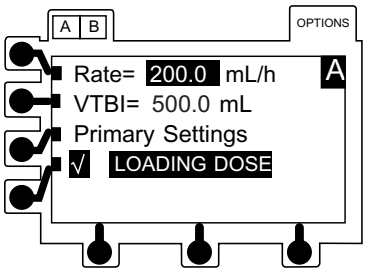
Programming (Continued)

4. If current value is appropriate, press **ENTER** key.

   OR

   To enter a new infusion rate, use numeric keypad and press **ENTER** key.

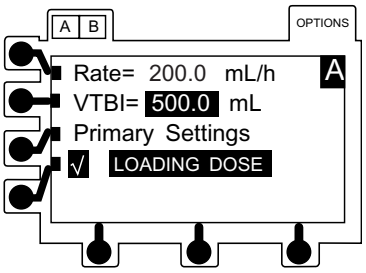
   - Loading Dose VTBI is highlighted.



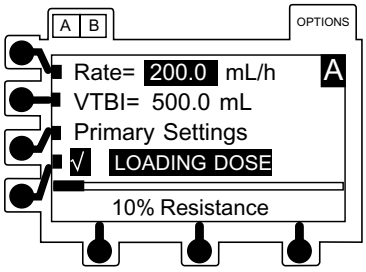
5. If current value is appropriate, press **ENTER** key.

   OR

   To enter a new VTBI, use numeric keypad and press **ENTER** key. ①



6. To start loading dose infusion, press **RUN/HOLD** key.
7. To briefly view current profile press ☑ soft key.
8. To briefly view primary settings (Pri Rate, Pri VTBI, Total VI) during loading dose infusion, press **Primary Settings** soft key.
9. To change Primary Settings during a loading dose infusion, press **Primary Settings** soft key.
10. Press soft key next to parameter to be edited.
    - Current value is highlighted.



11. Make changes:
    a. To enter a new value, use numeric keypad.
    b. To reset volume infused to 0.0 mL, press **CLEAR** or **0** (zero) key.
12. To accept new value, press **ENTER** key.
13. When complete:
    - **Loading Dose Complete** is displayed.
    - Pump returns to **Primary Infusion**.

NOTE:

① The Loading Dose VTBI must be less than the primary VTBI.

Multi-Dose

This feature allows 1 to 24 infusions to be preprogrammed with the same rate and volume, to be delivered at equally spaced intervals, over a period of up to 24 hours. It also offers a delayed start option up to 8 hours and a Dose Complete Alert Option. These features can be turned on or off.

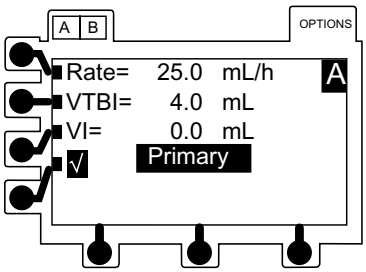
This program requires another infusing line to keep the vein open between programmed doses since there is no KVO infusion between doses or following program completion.

CAUTION

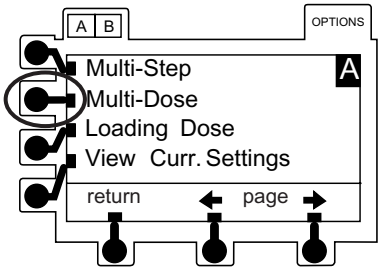
Guardrails® drug dosing limits are available only within the **New Guardrails Drug** or **New Guardrails IV Fluids** option. Dosing limits do not apply when using Multi-Dose programming. Profile configurable options, as defined in the Data Set, do apply.

Programming

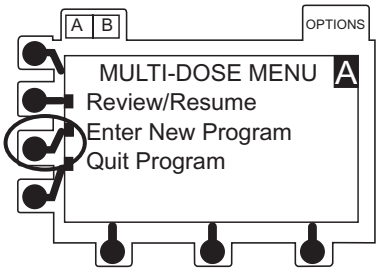
1. Select desired channel, as necessary. Channel must be on hold in primary mode.



2. Press **OPTIONS** key.
3. Press **Multi-Dose** soft key.



4. Press **Enter New Program** soft key.



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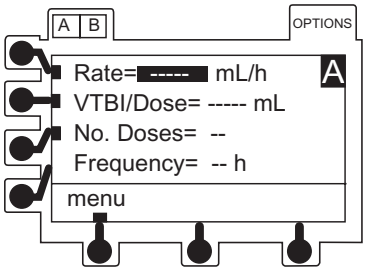
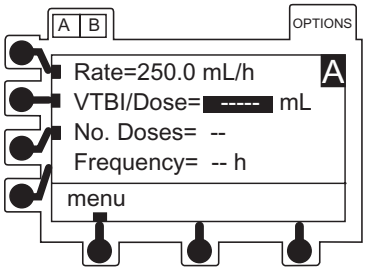
Programming (Continued)

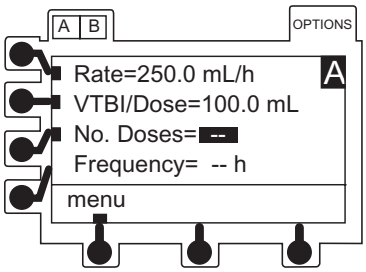
- Setup page appears with infusion rate highlighted.



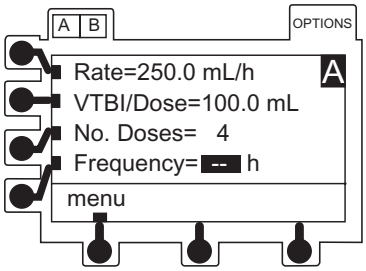
5. To enter infusion rate, use numeric keypad. Press **ENTER** key.



6. To enter VTBI/Dose, use numeric keypad. Press **ENTER** key.



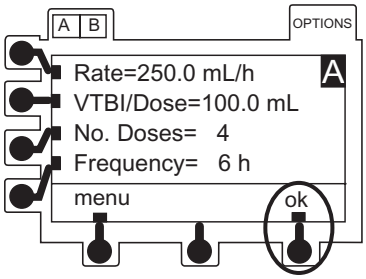
7. To enter number of doses, use numeric keypad. Press **ENTER** key.



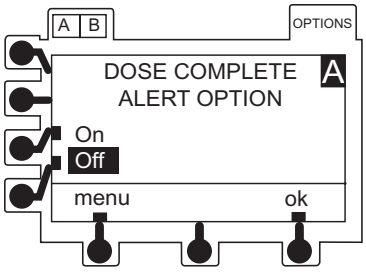
8. To enter dose frequency (time interval from start of one dose until start of next), use numeric keypad. Press **ENTER** key.

Programming (Continued)

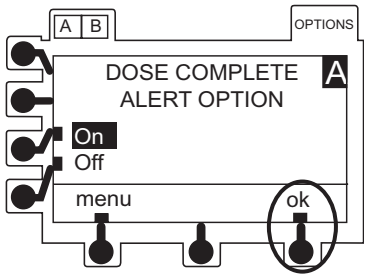
9. Verify that all parameters are correct then press **ok** soft key.



- If Dose Complete Alert Option is enabled, **DOSE COMPLETE ALERT OPTION** page appears.



10. To select **On** or **Off**, use soft keys.
11. To continue programming, press **ok** soft key. ①
    - To start first dose immediately, see “Starting First Dose Immediately After Programming”.
    - To delay start of first dose, see “Delaying Start of First Dose”.

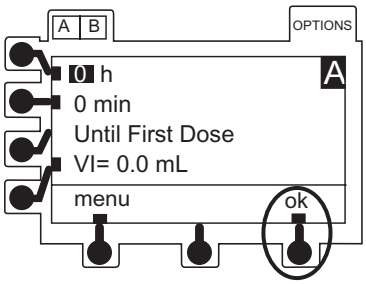


NOTE:

① All doses must be programmed to start within 24 hours.

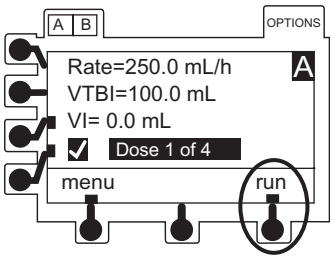
Starting First Dose Immediately After Programming

1. A displayed time of 0 hours, 0 minutes identifies that first dose starts immediately after programming.
2. To approve and advance to main hold page, press **ok** soft key.



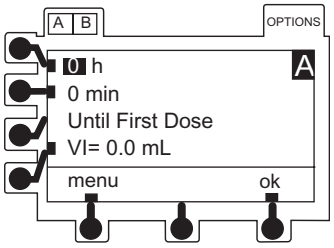
Starting First Dose Immediately After Programming (Continued)

3. To start infusion, press **RUN/HOLD** key or **run** soft key.

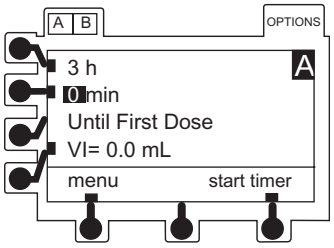


Delaying Start of First Dose

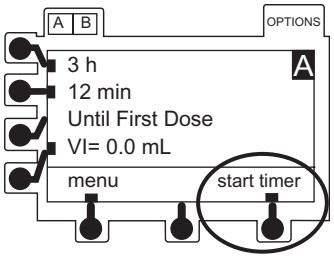
1. To enter number of hours until first dose, use numeric keypad. Press **ENTER** key.



2. To enter number of minutes (0 to 59) until first dose, use numeric keypad. Press **ENTER** key.



3. To advance to timer hold page, press **start timer** soft key.



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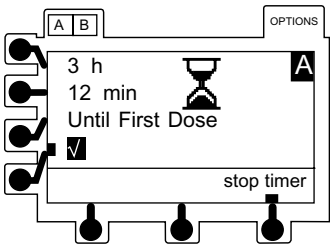
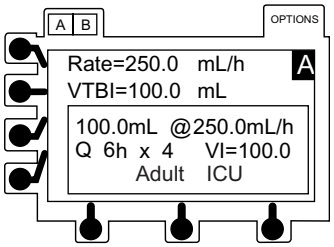
Delaying Start of First Dose (Continued)

- Hourglass icon flashes to indicate timer is counting down to start of dose.
- Dose automatically starts its infusion when timer reaches 0 hours, 0 minutes.

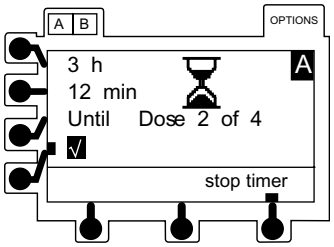


4. To briefly view Multi-Dose programmed information, press ✔ soft key.

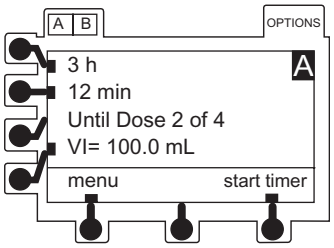


Changing Time Interval Until Next Dose

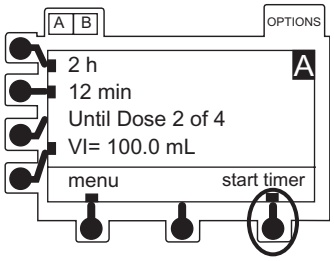
1. Press **stop timer** soft key.



2. To select a value for editing, press a soft key.



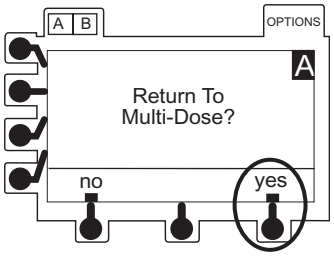
3. To enter new value, use numeric keypad. Press **ENTER** key.
4. When editing is complete, press **start timer** soft key.



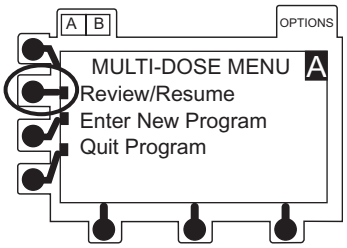
Multi-Dose (Continued)

Resuming an Interrupted Multi-Dose

1. Select desired channel, as necessary.
2. Select New Patient and Profile Options, as necessary. ①
   - **Return To Multi-Dose?** page appears.
3. Press **yes** soft key.
   - Pressing **no** soft key returns screen to primary setup page.



4. To access setup parameters, press **Review/Resume** soft key.
   - If infusion was in progress when interrupted, see "If Infusion Was In Progress When Interrupted".
   - If infusion was not in progress when interrupted, see "If Infusion Was Not In Progress When Interrupted".

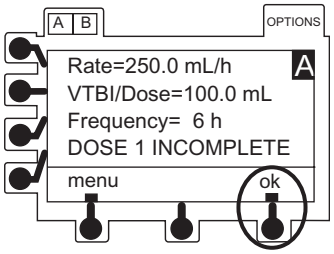


NOTE:

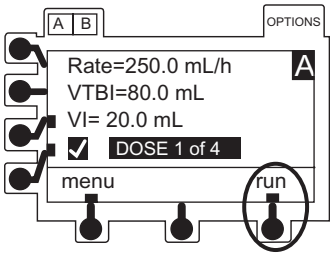
① Previous programming parameters will be preserved only if current profile is accepted and **NEW PATIENT?-NO** is selected.

If Infusion Was in Progress When Interrupted

1. To approve and advance to main hold page, press **ok** soft key.



2. To resume infusion, press **RUN/HOLD** key or **run** soft key.

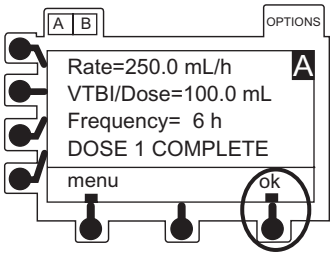


Multi-Dose (Continued)

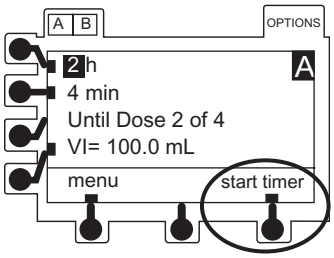
Resuming an Interrupted Multi-Dose (Continued)

If Infusion Was Not in Progress When Interrupted

1. Press **ok** soft key.



2. Edit time to delivery of next dose, as necessary.
3. To begin timer's countdown to delivery of next dose, press **start timer** soft key.



4. When final dose is complete:
   - **Dose _ of _ Complete** displays until user takes action.
   - No **Continuous Infusion** or **KVO Rate** occurs.

Multi-Step

The Multi-Step feature allows a sequential drug delivery program (up to 9 steps) to be set, delivering volumes of fluid at different rates during each step. This allows the instrument parameters to be set up once and to deliver a sequence eliminating the need to change the rate and VTBI after each infusion step.

The infusion may be programmed in either rate and volume or volume and time. At completion of the last programmed step, the channel switches to the preset KVO rate or remains at the current rate, whichever is less.

CAUTION

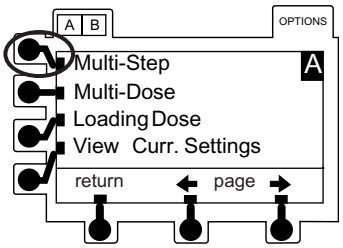
Guardrails® drug dosing limits are available only within the **New Guardrails Drug** or **New Guardrails IV Fluid** option. Dosing limits do not apply when using Multi-Step programming. Profile configurable options, as defined in the Data Set, do apply.

Programming

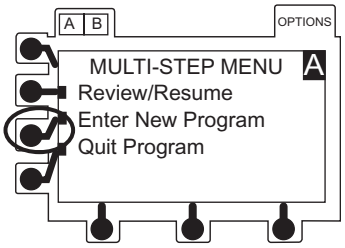
1. Select desired channel, as necessary. Channel must be on hold in primary mode.
2. Press **OPTIONS** key.

Programming (Continued)

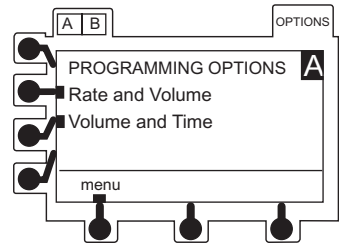
3. Press **Multi-Step** soft key.



4. Press **Enter New Program** soft key.

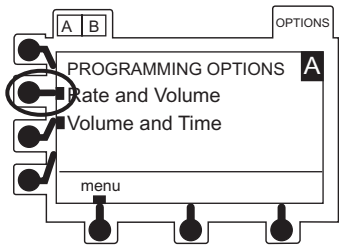


5. Determine setup method:
   - **Rate and Volume:** Instrument calculates step infusion time. Proceed to "Programming by Rate and Volume".
   - **Volume and Time:** Instrument calculates rate. "Proceed to Programming by Volume and Time".

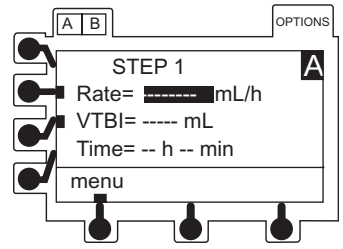


Programming by Rate and Volume

1. Press **Rate and Volume** soft key.

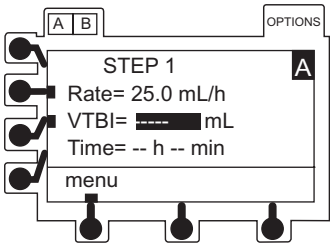


   - Step 1 of infusion sequence displays.

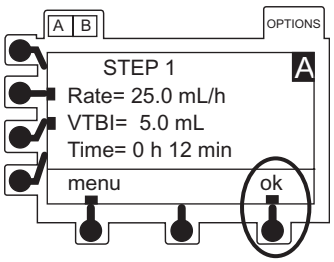


Programming by Rate and Volume
(Continued)

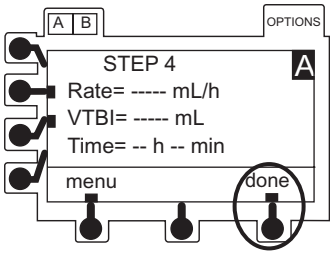
2. To enter a rate, use numeric keypad. Press **ENTER** key.



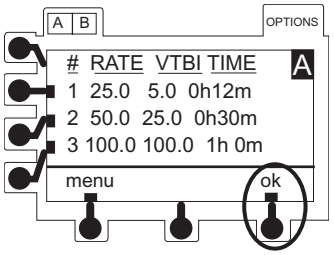
3. To enter VTBI, use numeric keypad. Press **ENTER** key.
   - Time in hours and minutes is automatically calculated and displayed.
4. To approve all displayed information and advance to step 2 of infusion sequence, press **ok** soft key.



5. To set up each additional step of infusion sequence, repeat steps 2 through 4.
6. When all steps have been entered and accepted, press **done** soft key.
   - Review page(s) display 3 sequence steps at a time.

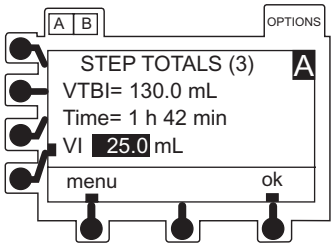


7. To approve and advance through review page(s), press **ok** soft key.

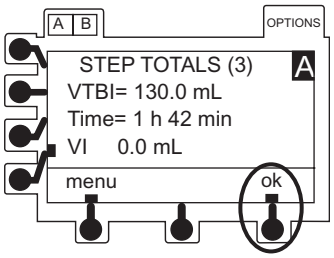


Programming by Rate and Volume (Continued)

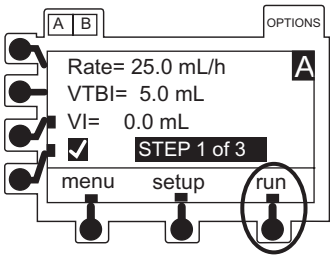
8. To clear VI, if desired, press **CLEAR** or **0** (zero) key. Press **ENTER** key.



9. To accept **STEP TOTALS** page, press **ok** soft key.

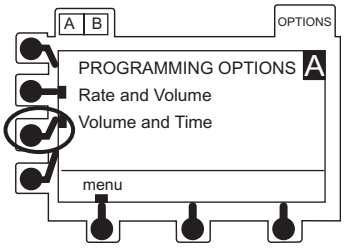


10. To start Multi-Step infusion program, press **run** soft key or **RUN/HOLD** key.



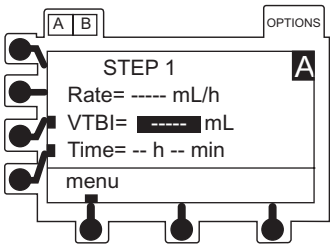
Programming by Volume and Time

1. Press **Volume and Time** soft key

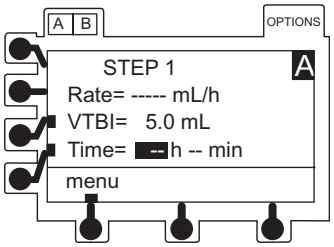


Programming by Volume and Time

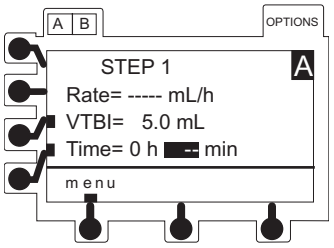
- Step 1 of infusion profile displays.
- VTBI is highlighted.



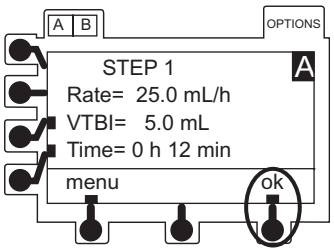
2. To enter VTBI, use numeric keypad. Press **ENTER** key.
   - Time (hours) is highlighted.



3. To enter hours, use numeric kepad. Press **ENTER** key.
   - Time (minutes) is highlighted.



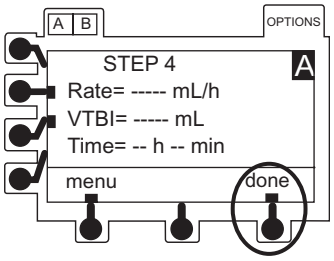
4. To enter minutes (0-59), if desired, use numeric keypad. Press **ENTER** key.
   - Volumetric rate is automatically calculated and displayed.
5. To approve all displayed information and advance to STEP 2 of infusion profile, press **ok** soft key.



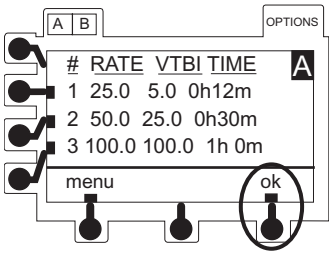
6. To set up each additional step of infusion profile, repeat steps 1 through 4.

Programming by Volume and Time
(Continued)

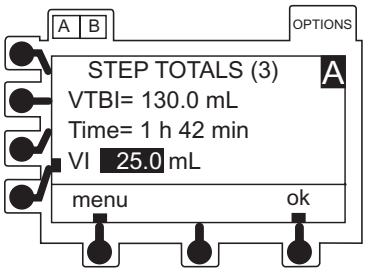
7. When all steps have been entered and accepted, press **done** soft key.
   - Review page(s) display 3 profile steps at a time.



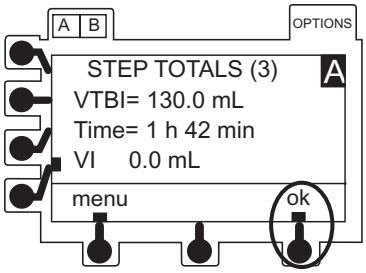
8. To approve and advance through review page(s), press **ok** soft key.



9. To clear VI, if desired, press **CLEAR** or **0** (zero) key. Press **ENTER** key.



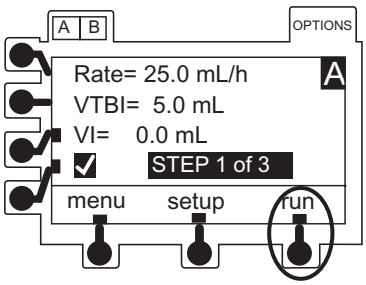
10. To approve STEP TOTALS page, press **ok** soft key.



Programming (Continued)

Programming by Volume and Time (Continued)

11. To start Multi-Step infusion program, press **RUN/HOLD** key or **run** soft key.

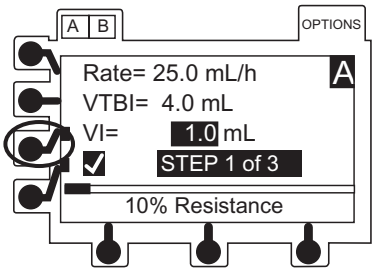


Making Changes During Multi-Step

Select the desired channel, as necessary. The channel does not need to be on hold to clear the VI or to view the totals remaining.

Clearing Volume Infused

1. Press **VI** soft key.

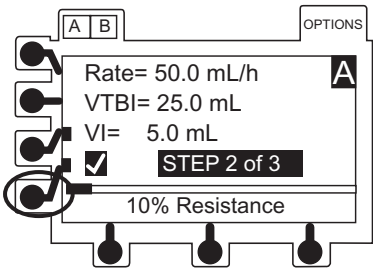


2. Press **CLEAR** or **0** (zero) key.
3. Press **ENTER** key.

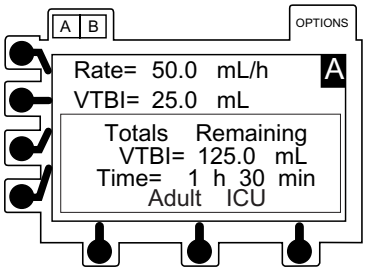
Making Changes During Multi-Step (Continued)

Viewing Totals Remaining

Press ☑ soft key.



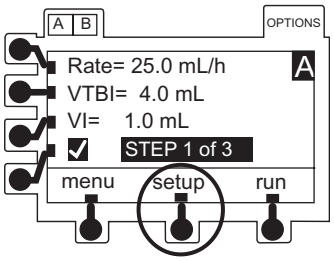
- Time and VTBI remaining in Multi-Step program display for a short interval.

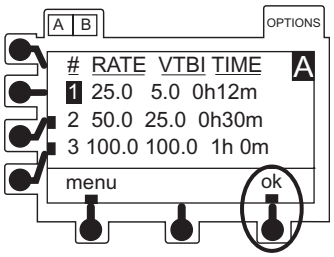


Viewing or Editing

The channel must be on hold to view or edit the steps in the program.

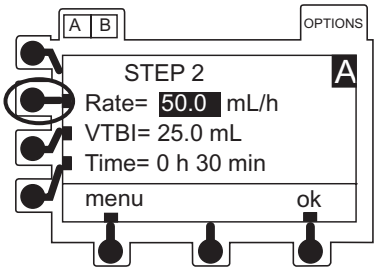
1. To place channel on hold, press **RUN/HOLD** key.
2. To return to review page(s), press **setup** soft key.
   - A tick mark (**I**) next to a step on review page(s) indicates it has not started.
   - Only steps having a (**I**) can be edited.
   - Completed steps, or a step in progress, do not have a (**I**).
   - A step number in progress is highlighted.
3. To advance through review page(s) of program, press **ok** soft key.



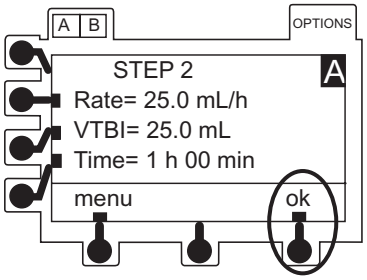


Viewing or Editing (Continued)

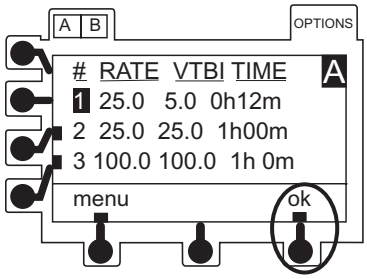
4. To select a step for editing, press a soft key.
5. To select value for editing, press a soft key.
6. To enter new value, use numeric keypad. Press **ENTER** key.



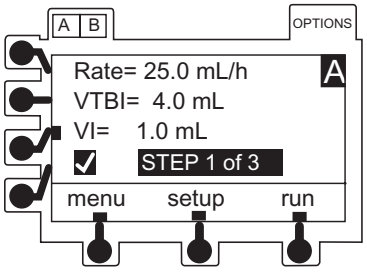
7. To return to review page(s) when programming is complete, press **ok** soft key.



8. To approve review page(s) and STEP TOTALS page, press **ok** soft key.



9. To resume infusion, press **RUN/HOLD** key or **run** soft key.

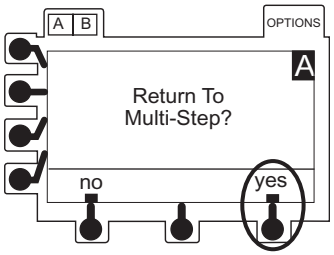


Multi-Step (Continued)

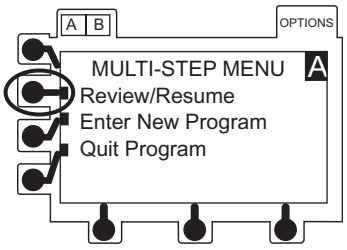
Resuming an Interrupted Multi-Step

The channel retains its place in the program if the instrument is turned off. The program can be restarted from step 1 or resumed where it left off.

1. Select desired channel, as necessary.
2. Select New Patient and Profile Options, as necessary. ①
   - **Return To Multi-Step?** page appears.②
3. Press **yes** soft key.
   - Pressing **no** soft key returns screen to primary setup page.



4. Press **Review/Resume** soft key.

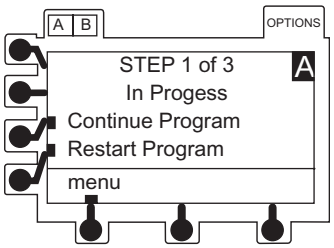


5. To resume program from point of interruption, press **Continue Program** soft key.

   OR

   To restart program at beginning of step 1, press **Restart Program** soft key.

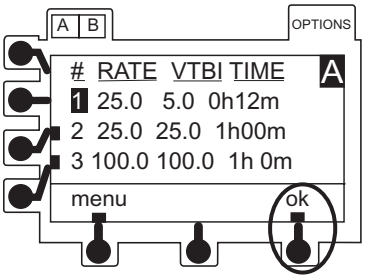
6 Verify all settings are correct. If a change is required, see "Making Changes During Multi-Step".



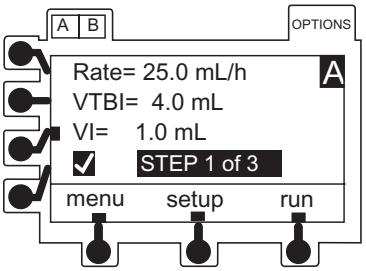
Multi-Step (Continued)

Resuming an Interrupted Multi-Step (Continued)

7. To approve review page(s) and STEP TOTALS page, press **ok** soft key.



8. To continue or restart program, press **RUN/HOLD** key or **run** soft key.



NOTES:

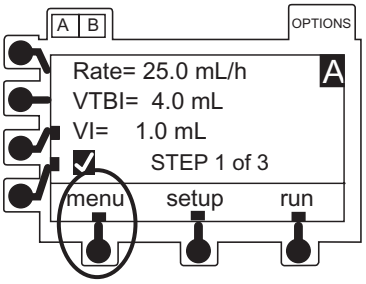
① Previous programming parameters will be preserved only if current profile is accepted and **NEW PATIENT?-NO** is selected.

② If resuming an infusion on a dual channel instrument with an infusion currently running, display goes directly to **Return To Multi-Step?** during startup.

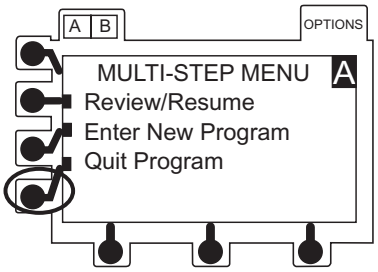
Quitting Multi-Dose and Multi-Step

The channel must be on hold or the last dose complete.

1. Press **menu** soft key.



2. To return to primary setup page, press **Quit Program** soft key. ①



NOTE:

① Primary setup page parameters may be different from those of the Multi-Dose or Multi-Step program. Verify all settings prior to resuming an infusion.

Secondary Infusion - NO Guardrails® Suite MX Protection

Introduction

See “Secondary Infusion With Guardrails® Suite MX Protection, Introduction and Setup".

Basic Secondary Infusion- Profiles Feature Enabled (On)

Primary infusion must be on hold to program secondary infusion.

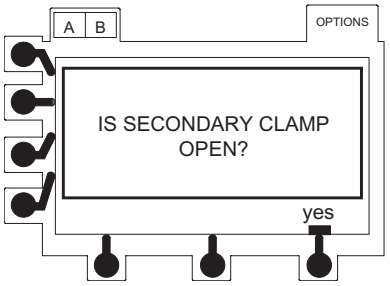
Secondary mode must be set to ON in the instrument system configuration settings. If secondary mode is OFF an invalid keypress tone sounds and "Secondary Not Allowed" displays when the **SEC** key is pressed.

1. Press **SEC** key
   - Secondary Menu displays
2. Press **Basic SEC** soft key
   - Basic secondary programming page displays.
   - VTBI field is highlighted.
3. To enter desired VTBI, use numeric keys then press **ENTER** key.
   - VI field is highlighted.
4. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key then press **ENTER** key.
   - Time is highlighted.
5. To enter a value, use numeric data entry keys to enter hours (0-99), then minutes (0-59). Press the **ENTER** key to accept each entry.
   - Time can be entered to calculate rate or if rate entry is desired, press **rate - time** soft key. It changes to **rate - time**, indicating that rate may be entered.
6. To continue programming press **ok** soft key.
   - A Secondary Clamp reminder message displays.

Secondary Infusion - NO Guardrails® Suite MX Protection (Continued)

Basic Secondary Infusion- Profiles Feature Enabled (On) (Continued)

7. Verify that secondary clamp is open before proceeding, then press **yes** soft key.
   - Basic secondary RUN/HOLD page displays.



8. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
9. To briefly view primary parameters (Pri rate, Pri VTBI) and current profile from RUN/HOLD page or during a running infusion, press ✔ soft key.
10. When secondary infusion is complete:
    - An audio tone sounds (if enabled).
    - Channel _ Secondary Complete briefly displays.
    - Infusion automatically transitions to primary rate.

Basic Secondary Infusion- Profiles Feature Not Enabled (Off)

1. Press **SEC** key
   - Secondary setup page displays.
   - Secondary rate is highlighted.
2. If current secondary infusion rate is appropriate, press **ENTER** key.

   OR

   To enter a new rate, use numeric keypad then press **ENTER** key.
   - Maximum rate for secondary infusion is 600 mL/h.
   - Secondary VTBI is highlighted.
3. If Secondary VTBI is appropriate, press **ENTER** key.

   OR

   To enter a new VTBI, use numeric keypad then press **ENTER** key.

Secondary Infusion - NO Guardrails® Suite MX Protection (Continued)

Basic Secondary Infusion- Profiles Feature Not Enabled (Off) (Continued)

4. To start secondary infusion, press **RUN/HOLD** key.
   - Secondary clamp reminder message displays.
5. Verify that secondary clamp is open before proceeding, then press **yes** soft key.
6. To briefly view primary settings during secondary infusion press **Primary Settings** soft key.
   - Primary rate (PriRate), primary volume to be infused (PriVTBI) and total volume infused (ToalVI) are displayed.
   - Display returns to normal secondary page after 6 seconds.
7. To change Primary settings, press soft key for **Pri Rate, Pri VTBI** or **Total VI** to freeze display and highlight desired value, then edit as usual (see "Primary Infusion - With Guardrails® Suite MX Protection", "Making Changes During Continuous Infusion").
8. When secondary infusion is complete:
   - An audio tone sounds (if enabled).
   - Channel _ Secondary Complete briefly displays.
   - Infusion automatically transitions to primary rate.

Dynamic Monitoring System

All features and options in this section are shown enabled. Options are enabled through the hospital Data Set profile configuration settings, or through the instrument configuration settings if the Profiles feature is not enabled (OFF).

The Dynamic Monitoring System provides the ability to monitor downstream pressure or resistance, allowing rapid detection of full and partial occlusions. Resistance monitoring eliminates the impact of patient elevation and flow rate to provide the most direct assessment of patency. Components of this system are:

- **Monitoring Options:** to select IV line/site monitoring modes of resistance, high resistance, and adjustable or fixed pressure.
- **Auto Restart Plus Feature:** allows instrument to automatically resume operation when specific instrument operating conditions are met.
- **Adjustable Resistance Alert:** to provide an early warning of increases in downstream flow resistance.
- **Adjustable Pressure Alarm:** to provide an early warning of increases in downstream pressure.
- **Trend Graph:** to display downstream pressure or flow resistance over time.
- **Pressure Baseline:** to provide a starting point from which to measure changes in system pressure.

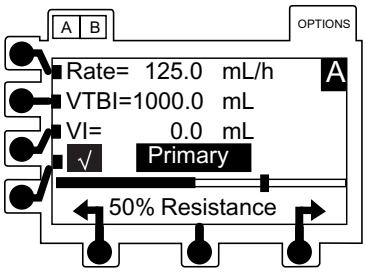
WARNINGS

- The SE Pump is designed to **stop fluid flow under alarm conditions**. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected. It is a **positive displacement delivery system**, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and will not alarm under infiltration conditions.
- Before each use, **verify the pressure or resistance alarm limits** are appropriate for the patient.

Monitoring Options - General

IV lines, catheters, and applications create various levels of resistance to flow. Monitoring mode options are available to meet each clinical need.

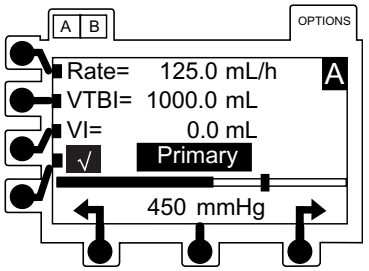
- **Resistance:** designed to monitor IV line/site resistance providing optimum sensitivity for most IV applications.
- **High Resistance:** designed to monitor IV line/site resistance with optimum sensitivity where higher resistance catheters are used.



Resistance Monitoring

Monitoring Options - General (Continued)

- **Adjustable Pressure:** designed to monitor IV line/site pressure and provide user-adjustable pressure alarm limits. Used for Precision Flow mode or for high resistance systems; such as, infusion through transducers, into dialysis systems and through highest resistance catheters. ①
- **Pressure:** designed to monitor IV line/site pressure and alarm based on a fixed pressure limit. ①



Pressure Monitoring

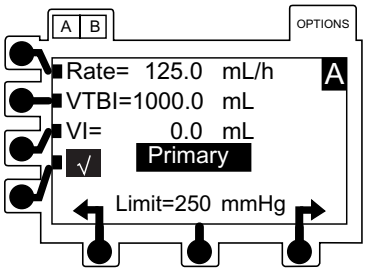
NOTE:

① Precision Flow: in fixed and adjustable pressure modes, the SE Pump provides enhanced flow continuity at rates below 50 mL/h.

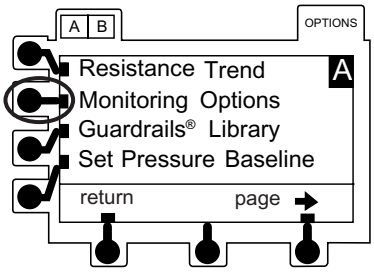
Selecting Monitoring Option

For dual channel instruments, select the desired channel as necessary. The bar graph and numeric displays are not available when the split screen is displayed.

1. Press **OPTIONS** key.



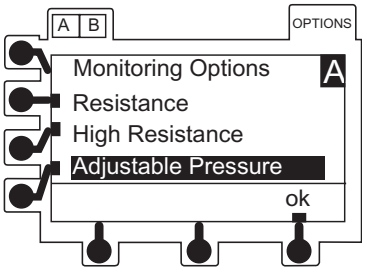
2. Press **Monitoring Options** soft key.



Monitoring Options - General (Continued)

Selecting Monitoring Option (Continued)

3. Press soft key for **Resistance**, **High Resistance** or **Adjustable Pressure**. ①

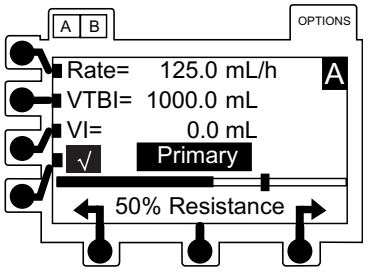


4. Press **ok** soft key. Display automatically returns to normal operating screen. ②

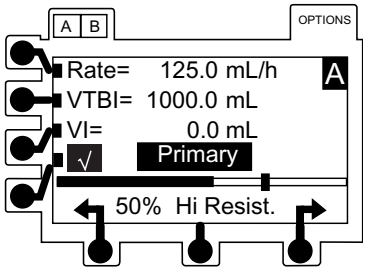
WARNING

Each time the instrument is turned on, verify and/or set the monitoring mode, resistance alert and/or pressure alarm limit. If the monitoring mode, resistance alert and/or pressure alarm limit are not verified, the instrument may not be operating with the desired occlusion detection parameter(s).

a. If **Resistance** option is selected, **% Resistance** displays below bar graph while infusing. ③



b. If **High Resistance** option is selected, **% Hi Resist.** displays below bar graph while infusing. ④

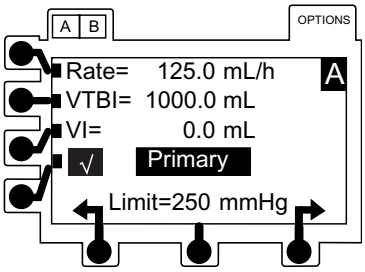


-- Continued Next Page --

Monitoring Options - General (Continued)

Selecting Monitoring Option (Continued)

c. If **Adjustable Pressure** option is selected, pressure system accuracy can be enhanced by ensuring no occlusion or other pressure source exists in IV line when activating **RUN/HOLD**. ⑤ ⑥



NOTES:

① If pressure limit adjustment is available, selection reads **Adjustable Pressure**; otherwise, it reads **Pressure**.

② While the channel is on, the selected option, resistance alert and pressure alarm thresholds remain in effect until changed by the operator.

③ Resistance alert limit may be adjusted using the soft keys located below the arrow symbols (see "Monitoring Options - Resistance Mode", “Resistance Alert”).

④ High Resistance alert limit may be adjusted using the soft keys located below the arrow symbols.

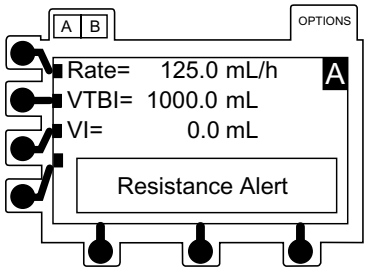
⑤ Pressure alarm limits may be adjusted when operating in Adjustable Pressure mode using the soft keys located below the arrow symbols (see "Monitoring Options - Pressure Mode", “Adjustable Pressure Alarm”).

⑥ Maximum pressure limit settings may be configured by qualified service personnel.

Monitoring Options - Resistance Mode

Detection of Downstream Occlusions

In the Resistance or High Resistance monitoring mode, a **RESISTANCE ALERT** condition occurs when the measured resistance reaches the alert limit.



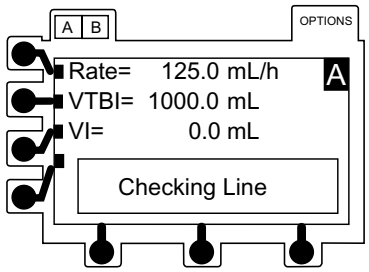
Detection of Downstream Occlusions (Continued)

An **OCCLUSION DOWNSTREAM** condition is detected when the measured resistance reaches 100% of scale. For the Resistance mode, 100% results from a resistance producing 2 mmHg per mL/h of flow. For the High Resistance mode, 100% results from a resistance producing 6 mmHg per mL/h flow.

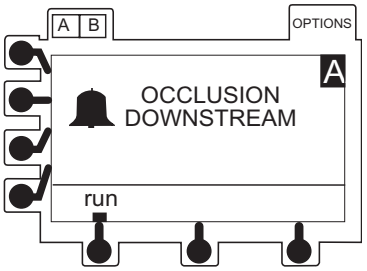
An **OCCLUSION DOWNSTREAM** condition is also detected when the configured pressure limit is exceeded. This limit may be set, by qualified service personnel, from 1 mmHg to 600 mmHg (Pressure Limit, Maximum).

When a Downstream Occlusion is detected, one of the following responses occur:

- If Auto Restart Plus feature is on, **Checking Line** message displays and audible tone sounds.



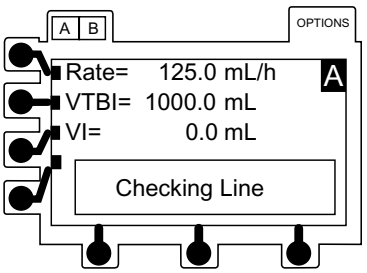
- If Auto Restart Plus feature is off, **OCCLUSION DOWNSTREAM** alarm occurs.



Auto Restart Plus Feature

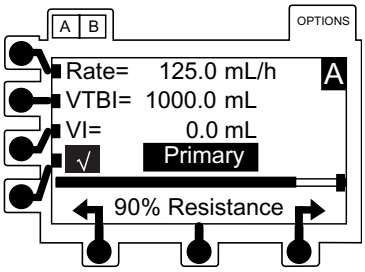
The Auto Restart Plus feature provides the ability to automatically continue an infusion if downstream resistance or pressure measurements indicate that an occlusion condition has cleared within a 40-second **Checking Line** period (excluding High Resistance Monitoring mode).

The **Checking Line** message and tone are presented when a resistance measurement exceeds the alarm threshold of 100%.

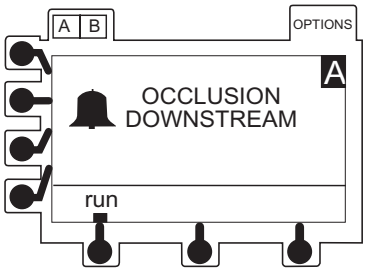


Auto Restart Plus Feature (Continued)

If resistance measurements initiate the **Checking Line** condition, the channel continues infusing in order to determine if the measured flow resistance has changed. If the measured flow resistance falls to any value below 100% within 40 seconds, the channel automatically resumes normal operating conditions (excluding High Resistance Monitoring mode).



Pressure measurements initiate the **Checking Line** period when the pressure exceeds the configured limit. If the pressure falls to less than one-third of the configured limit within 40 seconds, normal flow resumes. If the condition is not cleared, the **OCCLUSION DOWNSTREAM** alarm occurs and infusion stops until manually restarted.



This feature can be configured through the hospital Data Set to allow from 1 to 9 **Checking Line** restarts. After the programmed number of restarts has occurred or the 40-second **Checking Line** period has been exceeded, the channel immediately alarms **OCCLUSION DOWNSTREAM** when resistance or pressure conditions indicate an occlusion.

Resistance Alert

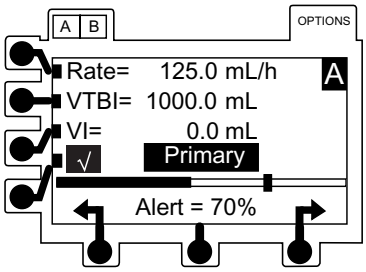
The Resistance Alert provides an early warning of increasing flow resistance. The Resistance Alert marker can be set from 0% to 100% of scale in 5% increments. This feature can be enabled or disabled and a power-on default alert level is set through the hospital Data Set.

To optimize the alert feature, it is advisable to set the alert level 20-30% higher than the initial displayed resistance. Read the resistance approximately 2 minutes after starting an infusion.

Setting Alert Marker

To numerically display present alert level marker, press either ↰ or ↱ soft key. Vertical line on resistance bar graph visually indicates alert level.

Each additional press of either arrow soft key increases or decreases alert level marker and numeric value by 5%.

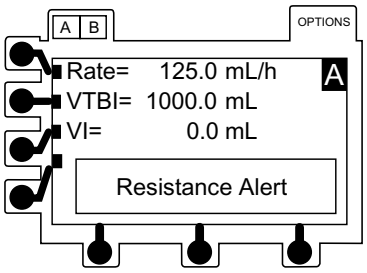


Resistance Alert

If Flow Resistance Exceeds Alert Level Marker

If flow resistance exceeds the alert level marker, a **Resistance Alert** message displays and an alert tone sounds. The channel continues to infuse, and the message and tone continue until one of the following resistance levels occurs:

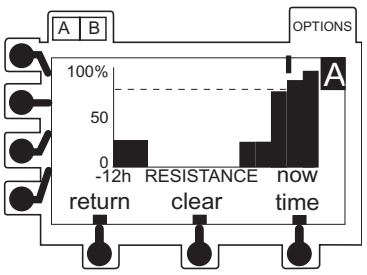
- IV line/site resistance falls below alert level marker.
- Resistance alert level marker increases above current measured resistance value.
- Resistance rises to 100%, initiating a **Checking Line** or **OCCLUSION DOWNSTREAM** condition.



Resistance Trend Graphs

In Resistance and High Resistance monitoring modes, a trend graph displays flow resistance over time. Trend graphs of 15 minutes, 1 hour, 4 hours and 12 hours are available during normal operation when enabled through the hospital Data Set.

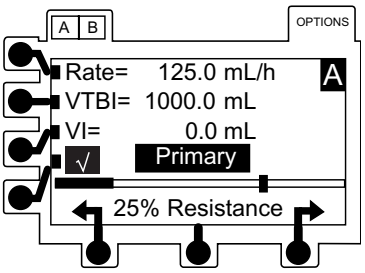
Downstream Occlusions are indicated by a tick mark (**I**) at the top of the trend screen.



Viewing Graphs

For dual channel instruments, select the desired channel, as necessary. The trend graph is not available while the split screen is displayed.

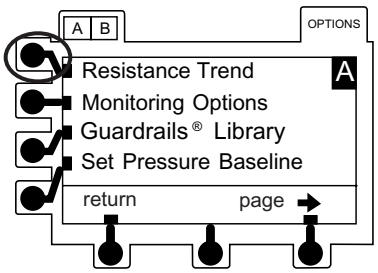
1. Press **OPTIONS** key.



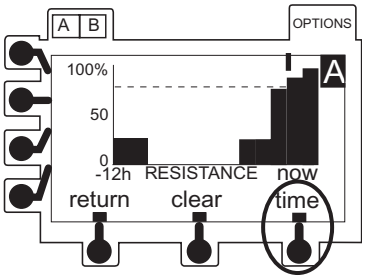
Resistance Trend Graphs (Continued)

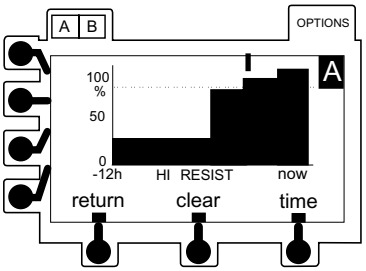
Viewing Graphs (Continued)

2. Press **Resistance Trend** soft key.



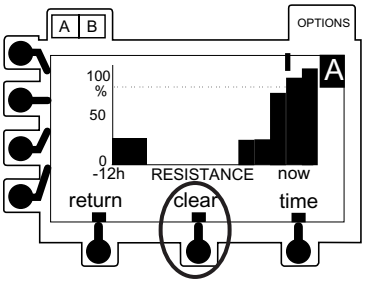
3. To change graph time frame, press **time** soft key.
   - A dashed horizontal line represents current resistance alert level.
   - Gaps in graph may indicate noninfusing conditions; such as, turned off, on hold, in alarm.
   - If channel has been placed in Pressure Monitoring mode for some portion of a trend graph window, resistance data is not available and zero values are plotted.
   - A tick mark (**I**) at top of graph indicates an occlusion.
   - When viewing Resistance Trend Graphs in High Resistance mode, **HI RESIST** displays under graph.





Clearing Graphs

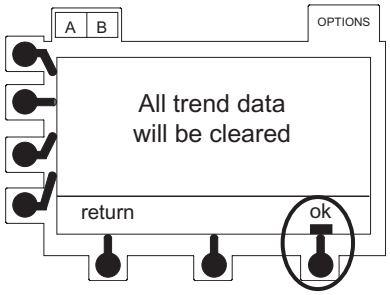
1. To clear graphed data, press **clear** soft key.



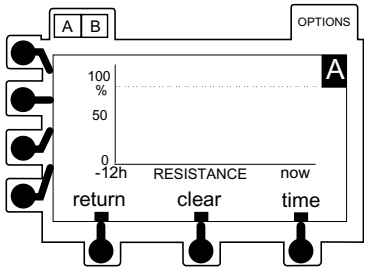
Resistance Trend Graphs (Continued)

Clearing Graphs (Continued)

2. Press **ok** soft key.



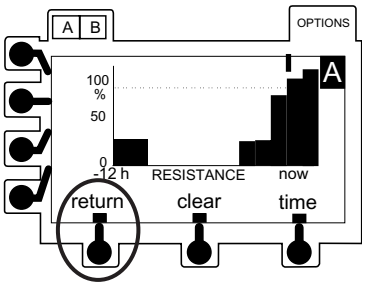
- All data is cleared from graphs.



Returning to Normal Operating Screen

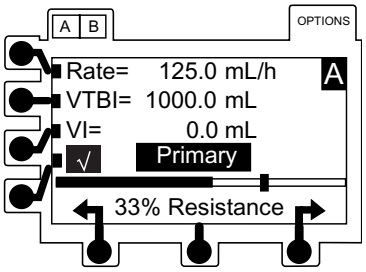
Press **return** soft key.

- Normal operating screen appears.



Following events also turn off trend graph:

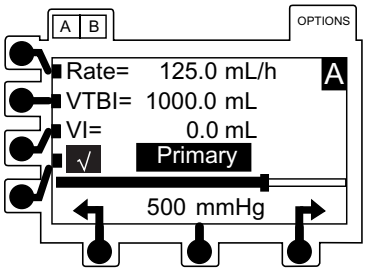
- Pressing **RUN/HOLD** key.
- An alarm.
- Dual channel instrument: pressing A B.
- Dual channel instrument: replaced with a split screen display after 1 minute if both channels are infusing.



Monitoring Options - Pressure Mode

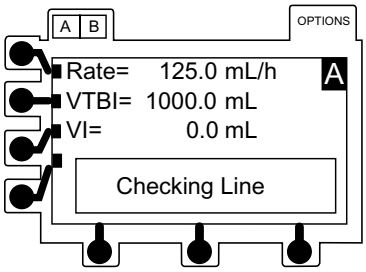
Detection of Downstream Occlusions

When using the Adjustable Pressure monitoring mode, a pressure alarm limit may be selected, in 25 mmHg increments, from 25 mmHg to the maximum configured pressure limit. When measured pressure exceeds this level, an **OCCLUSION DOWNSTREAM** condition occurs.

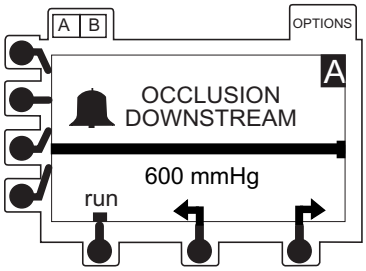


When a Downstream Occlusion is detected, one of following responses occurs:

- If Auto Restart Plus feature is on, a **Checking Line** message appears, along with an audible tone. (Reference “Auto Restart Plus Feature” for further details.)

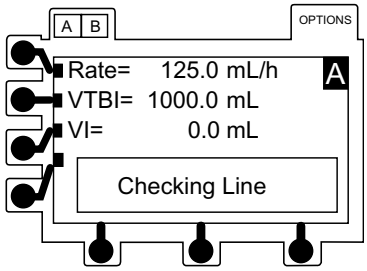


- If Auto Restart Plus feature is off, an **OCCLUSION DOWNSTREAM** alarm occurs.



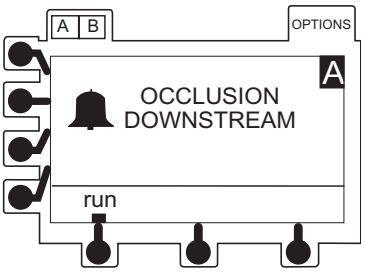
Auto Restart Plus Feature

The Auto Restart Plus feature provides the ability to automatically continue an infusion if downstream pressure measurements indicate that an occlusion condition has cleared within a 40-second **Checking Line** period (excluding High Resistance Monitoring mode).



Auto Restart Plus Feature (Continued)

The **Checking Line** message and tone occur whenever a pressure measurement exceeds the selected alarm threshold. If the pressure falls to less than one-third of the alarm limit within 40 seconds, normal flow resumes. The Adjustable Pressure mode allows control of the pressure alarm limit. If the condition is not cleared, the **OCCLUSION DOWNSTREAM** alarm occurs and infusion stops until manually restarted.



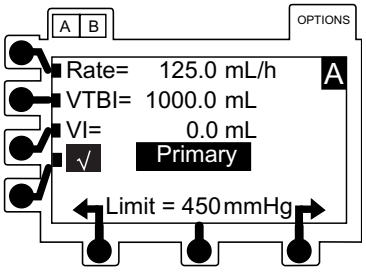
This feature can be configured through the hospital Data Set to allow from 1 to 9 **Checking Line** restarts. After the programmed number of restarts has occurred or the 40-second **Checking Line** period has been exceeded, the channel immediately alarms **OCCLUSION DOWNSTREAM** when resistance or pressure conditions indicate an occlusion.

Adjustable Pressure Alarm

In the Adjustable Pressure monitoring mode, the pressure alarm limit may be varied from 25 mmHg to the maximum configured pressure limit, in 25 mmHg increments. A default alarm level and a maximum pressure limit are set through the hospital Data Set profile configuration settings or through the instrument confirmation settings if the Profiles feature is not enabled (OFF).

Setting Alarm Limit Marker

Pressing either arrow (↰ or ↱) soft key changes alarm limit by 25 mmHg in corresponding direction. It is advisable to select an alarm limit appropriate for flow rate. At lower flow rates, alarm limit should be set lower, to shorten time to alarm.



Adjustable Pressure Alarm

Pressure Monitoring Using Automatic Baseline Calibration

The auto pressure baseline calibration remains in effect until the instrument is turned off, the latch is opened, the set is reloaded, or the Set Pressure Baseline function is performed.

- First activation of **RUN/HOLD** for a new infusion automatically establishes a pressure baseline based on current system pressure. An optimal baseline is maintained upon subsequent activations of **RUN/HOLD**, as follows:
  - If current system pressure is same or higher than original baseline, pressure baseline does not change.
  - If current system pressure is less than original baseline, system automatically resets to new system pressure value.
- Pressure measurement can be optimized, particularly at low flow rates (less than 3 mL/h), by pausing and restarting at least once every 2 hours (for example, when reprogramming VTBI). This allows pressure baseline to calibrate based on current system pressure.
- Prior to activation, ensure that pressure has not built up in IV line due to either occlusion or flow from other instruments through a common catheter. This will result in a more accurate pressure measurement.
- When loading a set connected to a small diameter catheter, wait at least 5 seconds after loading set before activating **RUN/HOLD**. This allows pressure generated by loading process to dissipate and sensor to stabilize. (Very small PICC catheters; such as, 28 gauge/1.2 French, may require 60 seconds or more for stabilization.)
- When multiple instruments are infusing through a common small diameter catheter, pressure measurement accuracy can be optimized by temporarily stopping all infusions, then restarting all instruments beginning with instrument delivering at lowest rate.

Pressure Baseline

The Pressure Baseline feature, when enabled through the hospital Data Set profile configuration settings, provides a real-time bar graph and numeric display of line pressure.

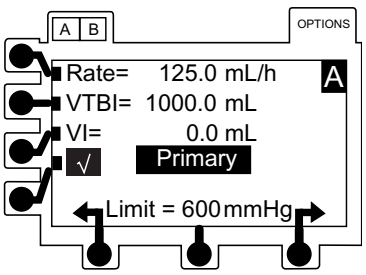
The pressure limit may be reduced if the pressure in the line is high or changing. This results in the pressure limit being lowered from the selected setting. If this occurs, first try to remove or reduce the downstream pressure. Following that, try to reload the set, wait 15 to 30 seconds and then perform a Set Pressure Baseline operation. The pressure baseline may need to be set a second time, after the pressure readings have stabilized.

Manually Setting Pressure Baseline While Operating in Adjustable Pressure Mode

For dual channel instruments, select the desired channel as necessary. The pressure bar graph is not shown when the split screen display is active.

For optimal results, set the baseline 15 minutes after starting an infusion. The pressure baseline can be optimized, particularly at low flow rates (less than 3 mL/h), by resetting the pressure baseline when the readings are negative. Check periodically for negative readings; for example, when programming VTBI. This allows the pressure baseline to calibrate based on current system pressure.

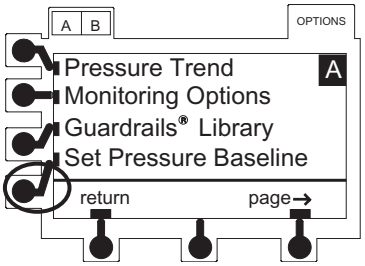
1. To place channel on hold, press channel's **RUN/HOLD** key. (All infusions connected to channel being base-lined must be on hold.)
2. Press **OPTIONS** key.



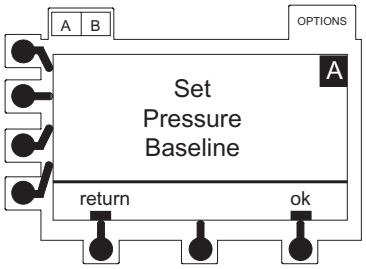
Pressure Baseline (Continued)

Manually Setting Pressure Baseline While Operating in Adjustable Pressure Mode (Continued)

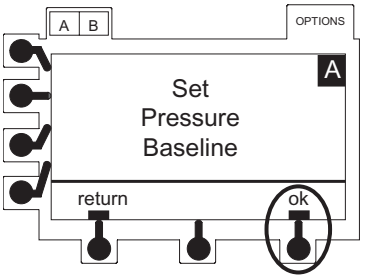
3. Press **Set Pressure Baseline** soft key. ①

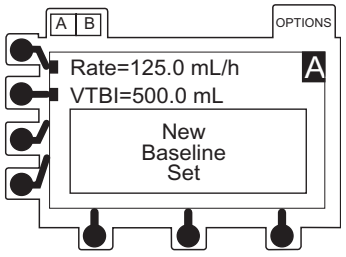


- **Set Pressure Baseline** screen appears.



4. Verify no pressure, due to occlusion or other infusions through a common line, is present in IV line at this time.
5. For best results, verify set outlet (for example, stopcock) is located at patient's heart level before continuing with next step.
6. Press **ok** soft key.

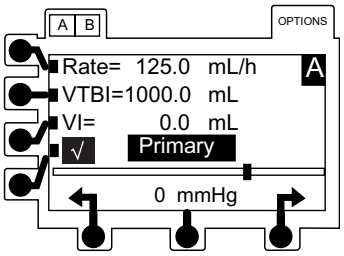




Pressure Baseline (Continued)

Manually Setting Pressure Baseline While Operating in Adjustable Pressure Mode (Continued)

7. Verify pressure readout is 0 (zero) mmHg. ②
8. To start infusion, press **RUN/HOLD** key. ③ ④ ⑤



NOTES:

① To return to the normal screen without setting the baseline, press **return** soft key.

② True baseline pressure will be zero or within a few mmHg of zero. If not, and the pressure is unstable, allow the pressure to drop to the lowest level and then repeat the Set Pressure Baseline process.

③ The pressure baseline calibration remains in effect until the instrument is turned off, the latch is opened, the set is reloaded, or the set Pressure Baseline function is performed again.

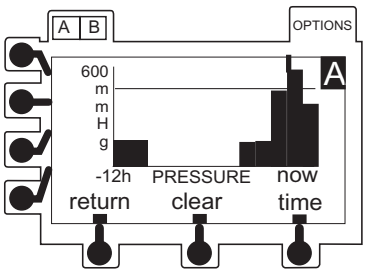
④ Setting the manual baseline overrides the auto baseline until the instrument is turned off, the latch is opened, set is loaded, or another manual baseline is set.

⑤ Setting a manual Pressure Baseline displays a horizontal real-time bar graph and numeric pressure readings. The vertical line on the pressure bar graph visually indicates the pressure alarm limit.

Pressure Trend Graphs

In Pressure Monitoring mode, a trend graph displays monitored pressure over time. Trend graphs of 15 minutes, 1 hour, 4 hours and 12 hours are available during normal operation when enabled through the hospital Data Set.

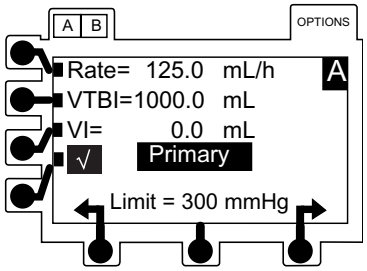
Downstream Occlusions, which occur in Pressure or Resistance modes, are indicated by a tick mark (**I**) at the top of the trend screen.



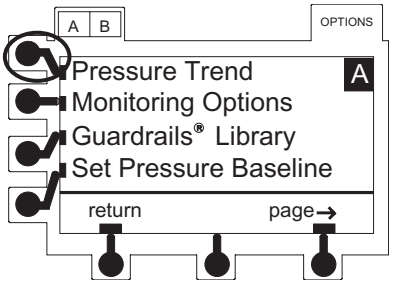
Pressure Trend Graphs (Continued)

Viewing Graphs

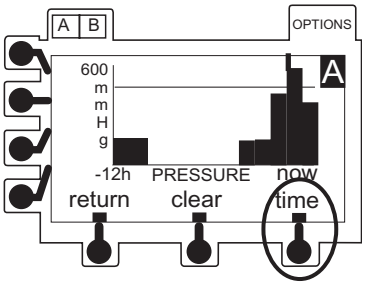
1. Dual channel instruments: Select desired channel, as necessary. Trend graph is not available while split screen is displayed.
2. Press **OPTIONS** key.

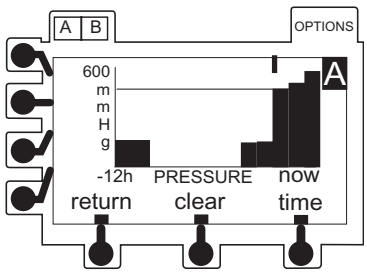


3. Press **Pressure Trend** soft key.



4. To change graph time frame, press **time** soft key.
   - A solid horizontal line represents current pressure alarm limit level.
   - Gaps in graph may indicate noninfusing conditions; such as, turned off, on hold, in alarm.
   - If channel has been placed in Resistance Monitoring mode for some portion of a trend graph window, pressure data is not available and zero values are plotted.
   - A tick mark (**I**) at top of graph indicates an occlusion.

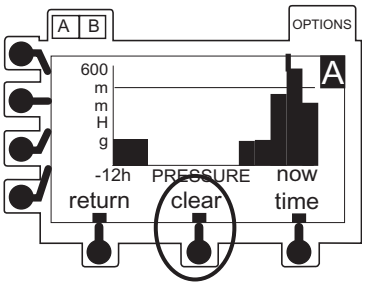




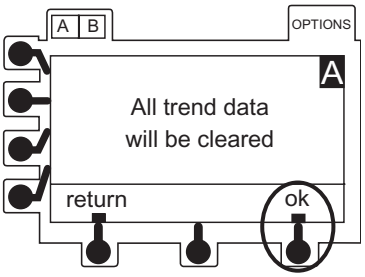
Pressure Trend Graphs (Continued)

Clearing Graphs

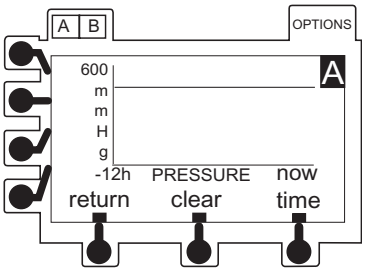
1. To clear graphed data, press **clear** soft key.



2. Press **ok** soft key.

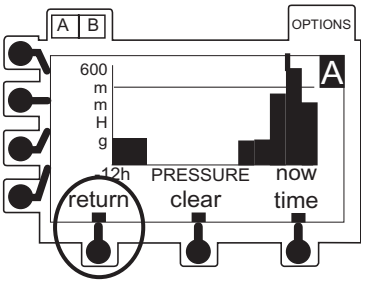


- All data is cleared from graphs.



Returning to Normal Operating Screen

Press **return** soft key.



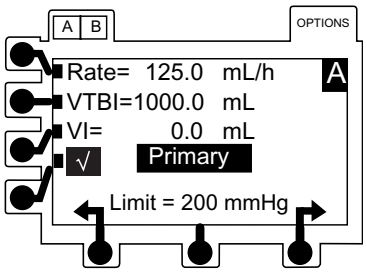
-- Continued Next Page --

Monitoring Options - Pressure Mode (Continued)

Pressure Trend Graphs (Continued)

Returning to Normal Operating Screen
(Continued)

- Normal operating screen appears.



Following events also turn off trend graph:

- Pressing **RUN/HOLD** key.
- An alarm.
- Dual channel instrument: pressing A B.
- Dual channel instrument: replaced with a split screen display after 1 minute if both channels are infusing.

Upstream Occlusions Detection

If the flow pathway between the fluid container and the Pressure Sensor is obstructed due to kinked tubing, a closed clamp or an improperly installed set, then an **OCCLUSION UPSTREAM** condition exists.

Depending on where the upstream path is occluded, flow may continue for a fraction of a mL before the **OCCLUSION UPSTREAM** alarm is produced. At high infusion rates, the instrument takes relatively little time to alarm. At low infusion rates, a longer time elapses before the instrument detects the condition and alarms. In either case, some flow continues from the instrument during the time prior to the alarm, due to the elastic behavior of the tubing between the occlusion site and the pumping mechanism.

If an **OCCLUSION UPSTREAM** alarm occurs, investigate and remedy the cause. Ensure that the upstream flow path (such as tubing) is free of obstructions, that any clamp is open and that the blue thumb clamp on the Flow Regulator is in the open (up) position before resuming the infusion.

Upstream Occlusions Detection (Continued)

When an upstream occlusion condition is detected:

- **OCCLUSION UPSTREAM** message appears.
- Audio alarm sounds and infusion stops.
- In certain conditions, upstream alarm system may briefly pause instrument and present **Checking Line** message for 10 seconds to confirm or rule out presence of an occlusion. If occlusion condition is determined not to exist, flow resumes and no alarm is produced.

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Audio Adjust

This feature allows the audio volume to be adjusted for alarms, alerts and KVO tone to either High, Medium or Low if all audio volume levels are enabled in the Profile configuration or in the instrument configuration settings and the Profiles features is set to OFF (not enabled).

1. Press soft key next to lower LCD display.

- Audio volume level displays in the lower LCD display.

Low

Medium

High

- Instrument can be configured to enable only Medium and High, or only High audio volume levels.

Tamper Resist

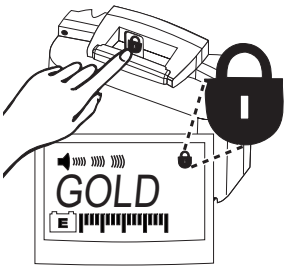
Locking and Unlocking Panel Lock

The panel lock feature helps prevent unauthorized changes to the instrument settings, including turning the instrument off. The panel lock feature must be set to ON in the hospital Data Set or in the instrument configuration settings if the Profiles feature is set to OFF (not enabled). To make changes or respond to an alarm, the panel lock must be turned off. The panel lock key ( ) is located behind the handle.

Turning Panel Lock Feature On

Press and hold until appears in lower display.

- Panel Locked appears in Main LCD Display if any other key is pressed.



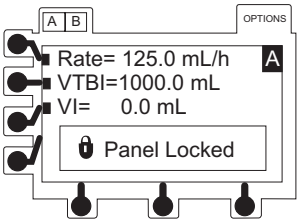
Tamper Resist (Continued)

Locking and Unlocking Panel Lock (Continued)

Turning Panel Lock Feature On (Continued)

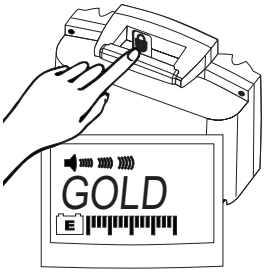
For dual channel instruments, while panel lock is activated, A/O, B/O and A B keys can be used to view settings.

Since panel lock must be inactivated to power down instrument, it is always off when instrument is powered on.



Turning Panel Lock Feature Off

Press and hold 🔒 until 🔓 disappears from lower display.



Warnings and Cautions

◄ DANGER ►

Explosion risk if used in the presence of flammable anesthetic agents or gases.

General

WARNINGS

- The SE Pump is designed to **stop fluid flow under alarm conditions**. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected. It is a **positive displacement delivery system**, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and will not alarm under infiltration conditions.
- The use of positive displacement infusion devices ported together with **gravity flow infusion** systems into a common IV site may impede the flow of common gravity-only systems, affecting their performance. Hospital/facility personnel must ensure the performance of the common IV site is satisfactory under these circumstances.
- **Each time the SE Pump is turned on**, verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument may not operate within the desired occlusion detection parameter(s).
- Before each use, **verify the pressure or resistance alarm limits** are appropriate for the patient.
- A new alarm or alert reinstates the **audio tone**.
- Assess patient's condition **before silencing an alarm**. Do not silence alarm if patient safety might be compromised.
- Disconnect from main (AC) and battery power when performing **maintenance**.
- **To disconnect from main (AC)**, unplug the power cord from the back of the instrument.

General (Continued)

WARNINGS

- Electrical shock hazard. **Do not open case**. Refer to qualified service personnel.

CAUTIONS

- The SE Pump is not intended to replace **supervision by medical personnel**. The user must become thoroughly familiar with the SE Pump features, operation and accessories prior to use.
- Always use a grounded, **three-wire receptacle**. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- Should an instrument or accessory be **dropped or severely jarred**, it should be immediately taken out of use and inspected by qualified service personnel, to ensure its proper function prior to reuse.
- If an instrument appears **damaged**, contact Cardinal Health for authorization to return it for repair.

Guardrails® Suite MX

WARNINGS

- The **Guardrails® Suite MX** incorporates dosing limits and instrument configuration parameters based on hospital/facility protocol. The software adds a **test of reasonableness** to drug programming based on the limits defined by the hospital/facility. Qualified personnel must ensure the appropriateness of drug dosing limits, drug compatibility, and instrument performance, as part of the overall infusion. **Potential hazards** include drug interactions, inaccurate delivery rates and pressure alarms, and nuisance alarms.
- When delivering an infusion with the Guardrails® Suite MX protection, **ensure the correct profile** (for patient care area) is selected prior to starting an infusion. Failure to select the appropriate profile could cause serious consequences.

Administration Sets

WARNINGS

- **When priming:**
  - Ensure patient is not connected.
  - Ensure air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

  Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.
- **Discard if** packaging is not intact or protector caps are unattached.
- **Use only sets dedicated** for use with the SE Pump. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard.

CAUTION

- Before operating instrument, verify that administration set is **free from kinks and installed correctly** in instrument.

Epidural Administration

WARNINGS

- **Epidural administration** of drugs other than those indicated for epidural use could result in serious injury to the patient.
- It is strongly recommended that the source container, administration set, and SE Pump used for **epidural drug delivery** be clearly differentiated from those used for other types of administration.

Epidural Administration (Continued)

WARNINGS

- The SE Pump can be used for epidural administration of **anesthetic and analgesic drugs**. This application is only appropriate when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only sets dedicated for use with the SE Pump, without a 'Y' connector or injection port, for epidural infusions.
  - Epidural administration of **anesthetic drugs**: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.
  - Epidural administration of **analgesic drugs**: Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

Electromagnetic Compatibility

WARNINGS

- Do not use the SE Pump near Magnetic Resonance Imaging (**MRI**).
- Use of any **accessory or cable** other than those specified may result in increased emissions or decreased SE Pump immunity.
- Do not use the SE Pump in a **hyperbaric chamber**.

CAUTIONS

- The instrument should not be used **adjacent or stacked with other equipment**. If adjacent or stacked use is necessary, the instrument should be observed to verify normal operation in the configuration in which it will be used.
- **Portable and Mobile RF communications** can affect Medical Electrical Equipment.

Electromagnetic Compatibility (Continued)

CAUTIONS

- The SE pump is intended for use under the supervision of healthcare professionals only. This is a CISPR 11 Class B device without the use of the Model 180 (Flow Sensor) and CISPR 11 Class A when the Model 180 (Flow Sensor) is used. In a domestic environment, this system **may cause radio interference**. Reorienting, relocating or shielding the system, or filtering the connection to the public mains network, are examples of steps that can be taken to reduce or eliminate interference.

Battery Management System

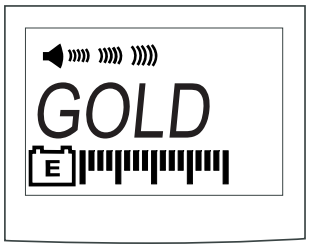
The Battery Management System incorporates features which enhance battery maintenance in order to maximize the life of the battery, reduce associated costs and increase instrument availability. The system provides:

- Green : lights when instrument is plugged in.
- Amber : flashes when instrument is operating on battery power.
- Automatic battery power: if instrument is unplugged or in the event of a power failure.
- Low battery alert: indicates battery depletion is imminent, beginning at least 30 minutes prior to a **BATTERY DEPLETED** alarm.

Maximum battery capacity, as well as optimal gauge accuracy, is reached after several complete charge/discharge/recharge cycles in the refresh process. It is recommended that the battery be fully charged/discharged/recharged, using the refresh cycle, before placing the instrument in use. Reference the Technical Service Manual for detailed information on the refresh cycle.

Battery Management System (Continued)

Battery Power Gauge and Indicator



The gauge indicates approximate battery run time remaining under current operating conditions. It is located in the lower display and is always on. To ensure a more accurate battery gauge reading, review the remaining battery run time 5 minutes after starting an infusion.

Battery run time may be affected by the operating mode, rate, monitoring options and back pressure. The gauge accuracy is based on the last refresh cycle and is affected by the number of charge/discharge/recharge cycles. The instrument label and battery gauge are always displayed, even when the instrument is turned off; however, the battery gauge does not represent the battery time remaining when the instrument is turned off.

Battery Recharge

The battery recharges whenever the instrument is plugged into an AC outlet. The battery can be replaced when charging capacity gets too low.

All batteries gradually lose their capacity to hold a charge over time and use. To maintain optimal battery performance, ensure the instrument is connected to AC power whenever possible, including when it is powered off or stored.

Following certain battery depleted conditions it is necessary to reset the internal clock so the CQI Reporter data integrity is maintained (see "Programming", "Programming and Navigation Tips", "Responding to Time Set Reminder".

Flow Sensor ①

The optional flow sensor notifies users of empty containers and/or upstream occlusions. A handle cap accessory is available for storing the flow sensor when not in use.

The flow sensor is not used for the first 25 mL delivered when changing from secondary to primary. This is to account for overfill of secondary containers.

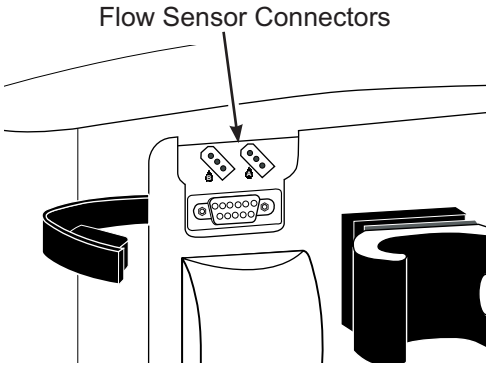
WARNING

The **protective cover** over the RS-232 connector must remain in place when not in use.

Flow Sensor (Continued)

If a flow sensor is not connected to the instrument, ensure protective plugs are installed at the connector site to prevent entry of foreign material.

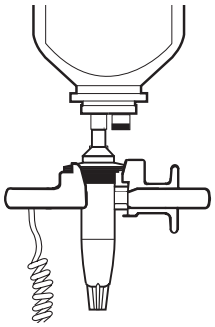
1. Plug a Model 180 Flow Sensor into applicable channel connector on back of instrument.



2. Attach flow sensor to upper portion of drip chamber.
   - When using flow sensor, correct placement is essential for proper operation. Some administration set drip chambers have a flange at top to which flow sensor can be attached. Attachment on flange ensures proper placement.

     Upper surface of flow sensor should be slightly below drop-forming orifice but above level of fluid in drip chamber.

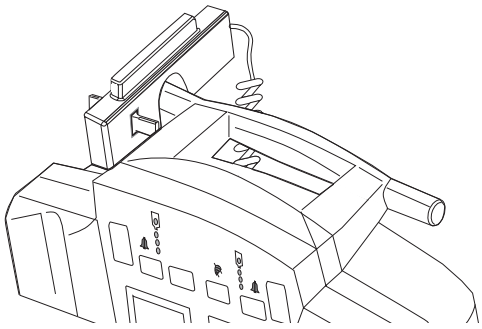
     Ensure drip chamber is at least 2/3 full and sensor optics are clean. Fluid level in drip chamber must be checked/re–established after each empty container condition
   - When using flow sensor option while ambulating or transporting a patient from one area to another, use care to avoid excessive swinging of solution container(s).



CAUTION

Infusing fluids which form smaller drops, through a 60 drops/mL set, at high rates may result in a **No Upstream Flow Detected** alarm. This is because the small, rapidly falling drops form a continuous stream which does not trigger the flow sensor. In this event, unplug the flow sensor from the instrument.

3. Attach flow sensor to instrument handle when not in use.



Flow Sensor (Continued)

4. Routinely clean flow sensor with warm water while actuating slider, then dry thoroughly.

CAUTION

Do not use solvents or cleaning agents. Damage to plastic parts of the flow sensor could occur.

NOTE:

① If the flow sensor option is in use, VTBI can be turned off by selecting VTBI, pressing **CLEAR** and then **ENTER** keys.

OR

Primary VTBI can be deleted from the primary mode setup page (see "General Information, System Configurable Options").

Alerts Counter ①

The instrument keeps a running count of Guardrails® Alerts that occur. This information may be viewed with the Alerts Counter feature.

Definitions ②

GR Alerts:	Total number of Hard Limit and Soft Limit Guardrails® alerts that occur.
GR Starts:	Total starts when a Guardrails® drug or Guardrails® fluid is selected. GR Start counter also increments if a rate or dose rate change occurs during a running infusion. A transition to KVO rate is not counted as a start.
Log % Full:	CQI log retained by instrument can hold up to 300 Guardrails® alerts and resolutions snapshots. The % full indication represents percentage of 300 available logged snapshots used. For example, if log currently contains 30 snapshots, % full indication is 10%. Log always retains most recent 300 snapshots, therefore, even if this indication is 100% full, subsequent Guardrails® alerts and resolution snapshots are stored and oldest ones are deleted to make space for newer ones.

Alerts Counter (Continued)

Definitions (Continued)

New Patients: Total number of new patients or profiles selected. Counter increments when **yes** to **New Patient?** screen prompt or a different profile at instrument power up is selected.

Overrides: Total number of Soft Limit Guardrails® alerts that are overridden. Counter increments when **yes** is selected in response to soft override alert prompt.

Soft Alerts: Total number of Soft Limit Guardrails® alerts that occur. Counter increments when either **yes** or **no** is selected in response to soft override alert prompt.

Total Starts: Total number of infusion starts. A start occurs when **run** key is selected from an inactive or paused condition.

NOTES:

① For dual channel instruments, the counters represent the total counts for both channels.

② These are the counter labels as they appear on the Main Display.

Viewing Alerts Counter

1. Press **OPTIONS** key.
2. Press **Alerts Counters** soft key.
3. To return to main display, press **return** soft key.

   OR

   To clear counter (reset all values to zero), press **clear** soft key.

   OR

   To view second event counter page, press **page** soft key.

   - Last cleared date displays.

Nurse Call (7130/7230 Only)

If the instrument is equipped with the optional nurse call feature, alarms and some alerts from the instrument are relayed to the hospital's existing nurse call system. No instrument operating features are changed. The instrument alarms with or without the nurse call installed.

Activating Nurse Call Feature

1. Plug nurse call cable into

on instrument back panel. ①
2. Press channel's **POWER** key.
   - Instrument beeps briefly to signal proper operation.
3. Plug nurse call cable into nurse call system.
4. Operate instrument as described in this document. ② ③

NOTES:

① A false remote alarm may occur if the nurse call plug is not properly inserted.

② All alarms and some alerts activate the nurse call system. The following alerts will not activate the nurse call system: Checking Line, Load Dose Complete, Secondary Complete.

③ Disconnecting the nurse call cable from the wall or turning off the instrument activates the nurse call system. Disconnecting the nurse call cable from the instrument will not activate the nurse call system.

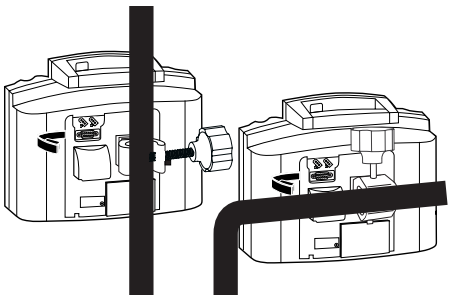
If an Alarm Occurs

1. Determine cause and appropriate corrective action (see "Troubleshooting and Maintenance", "Alarms, Alerts, Prompts").
2. Reset nurse call system, as required.

Pole Clamp

The uniquely designed pole clamp adapts to a wide variety of surfaces (such as, poles, bed rails) to provide greater versatility and to simplify transports.① ② It features:

- 360º rotation in 90º increments
- ergonomically designed knob
- accommodates diameters from 15 to 35 millimeters



NOTES:

① The illustrated pole clamp knob may not reflect the knob in use on the instrument.

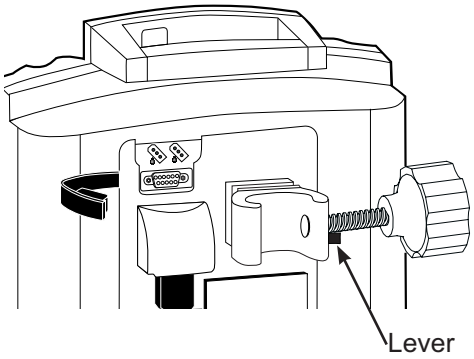
② When using multiple instruments, care should be taken to evenly distribute the instruments to ensure stability.

WARNING

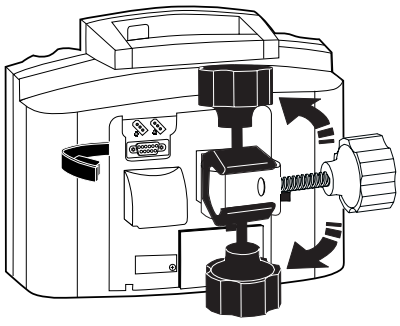
To **ensure proper occlusion detection**, DO NOT operate the instrument tilted back more than 45º from the upright position.

Changing Pole Clamp Orientation ①

1. Press and hold rotation lever.



2. Reposition clamp.
3. Release lever at desired position.



NOTE:

① The illustrated pole clamp knob may not reflect the knob in use on the instrument.

RS-232 Computer Link

The optional Computer Link feature allows a hospital/facility computer to interact with the instrument. The computer cannot start or stop the instrument, set the rate, or make any change in status. The feature may be enabled or disabled by qualified personnel in the instrument configuration settings. If the feature is enabled (On) the user may select Monitor, to allow the computer to receive information from the instrument, or Off. When Off is selected, the computer cannot communicate with the instrument.

To assure continued electromagnetic compatibility performance, the communications cable attached to the instrument should be no longer than 1 meter, have fully shielded connector housings, and have a 100% coverage braid/foil shield attached to the connector housings around the signal conductors with the cable jacket.

Connecting to a Computer

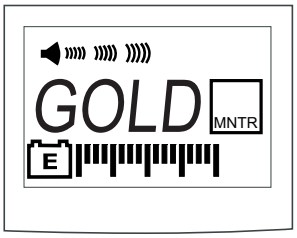
1. Press **OPTIONS** key.
2. To advance to next page, press **page** soft key.
3. Press **Computer Link** soft key.
4. Press **Monitor** soft key.
5. Press **ok** soft key.
6. Connect an RS-232 cable from hospital computer to RS 232 port on instrument back panel.
   - During communication between host computer and instrument, **MNTR** (Monitor Mode) appears in lower LCD. ①
   - If communication is interrupted, **MNTR** flashes for 60 seconds.

NOTE:

① MNTR remains in the lower display once the mode is selected and communication with the computer has been established.

WARNINGS

- **Use of any accessory or cable** other than those specified may result in increased emissions or decreased SE Pump immunity.
- The **protective cover** over the RS-232 connector must remain in place when not in use.
- **Only equipment that complies with IEC EN 60601-1 or UL 1069** (approved medical or hospital signaling equipment) should be connected to the RS-232 connector.



RS-232 Computer Link (Continued)

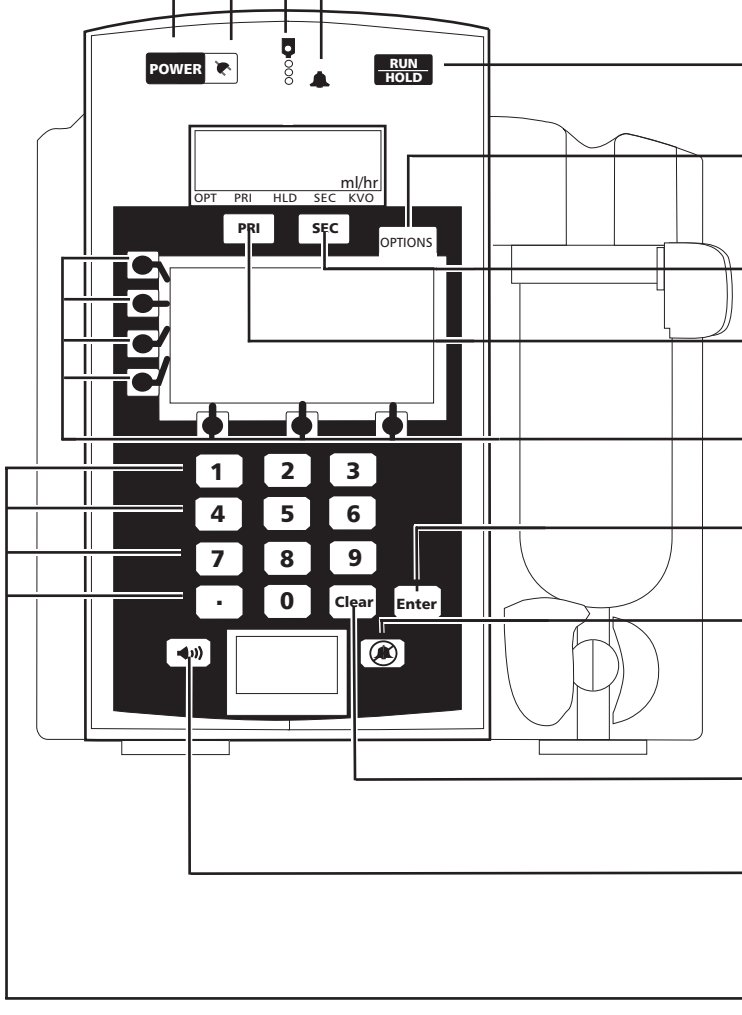
Disconnecting from a Computer

1. Press **OPTIONS** key.
2. To advance to next page, press **page** soft key.
3. Press **Computer Link** soft key.
4. Press **Off** soft key.
5. Press **ok** soft key.
6. Disconnect RS-232 cable from

port on instrument back panel.

Operating Features, Controls, Indicators

Models 7130/7131



Power Key: Turns instrument on and off.

Power Indicator:
Green = Plugged in and charging.
Flashing Amber = Battery power.

Infusing Indicator: Indicates instrument is infusing.

Alarm Indicator: Indicates instrument is in alarm and has stopped infusing.

RUN/HOLD Key: Starts and stops infusion.

OPTIONS Key: Accesses additional features.

Secondary (SEC) Key: Selects secondary mode.

Primary (PRI) Key: Selects primary mode.

Soft Keys: Reference “Programming and Navigation Tips”.

ENTER Key: Accepts value or selection entered.

Silence Key: Silences audible alarm or alert for 2 minutes; message remains on screen. New alarm or alert reinstates audible tone.

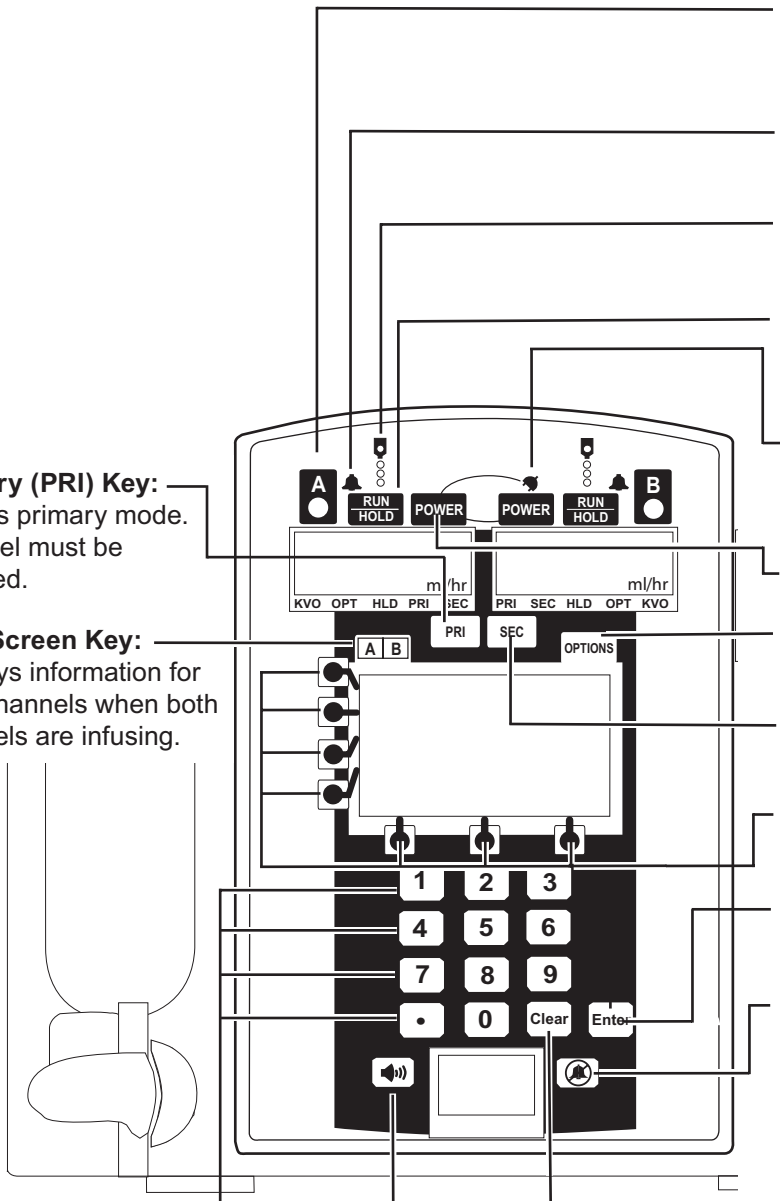
CLEAR Key: Clears selected numeric value.

Audio Volume Key: Sets audio volume for alarms, alerts and KVO tone. Press key to adjust volume.

Numeric Keypad: Enters/changes values.

Operating Features, Controls, Indicators (Continued)

Models 7230/7231



Channel Select Keys/Indicators: Select channel A or B. Light to indicate which channel is selected.

Alarm Indicators: Indicate a channel is in alarm and has stopped infusing.

Infusing Indicators: Indicate a channel is infusing.

RUN/HOLD Keys: Start and stop infusion on selected channel. To restart, channel must be selected.

Power Indicator:
Green = Plugged in and charging.
Flashing Amber = Battery power.

Primary (PRI) Key: Selects primary mode. Channel must be selected.

Power Keys: Turn channels on and off.

Split Screen Key: Displays information for both channels when both channels are infusing.

OPTIONS Key: Accesses additional features.

Secondary (SEC) Key: Selects secondary mode.

Soft Keys: Reference “Programming and Navigation Tips”.

ENTER Key: Accepts value or selection entered.

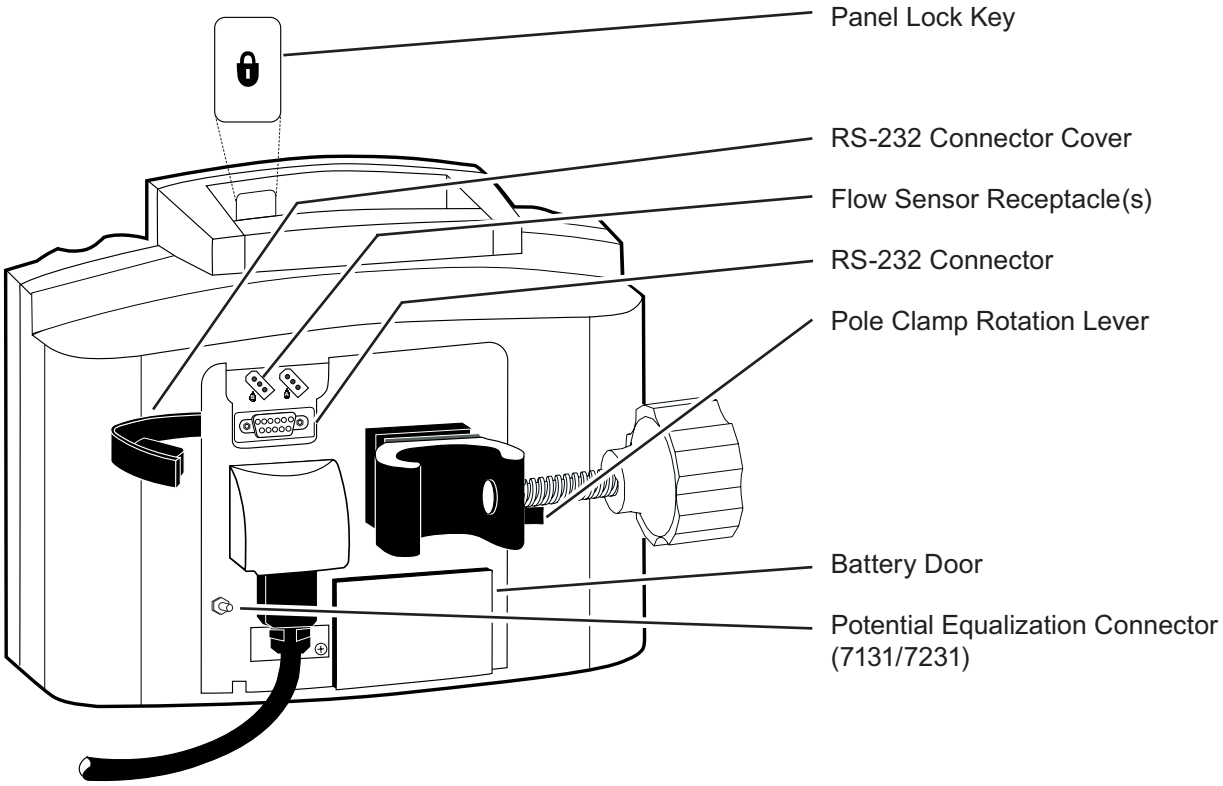
Silence Key: Silences audible alarm or alert for 2 minutes; message remains on screen. New alarm or alert reinstates audible tone.

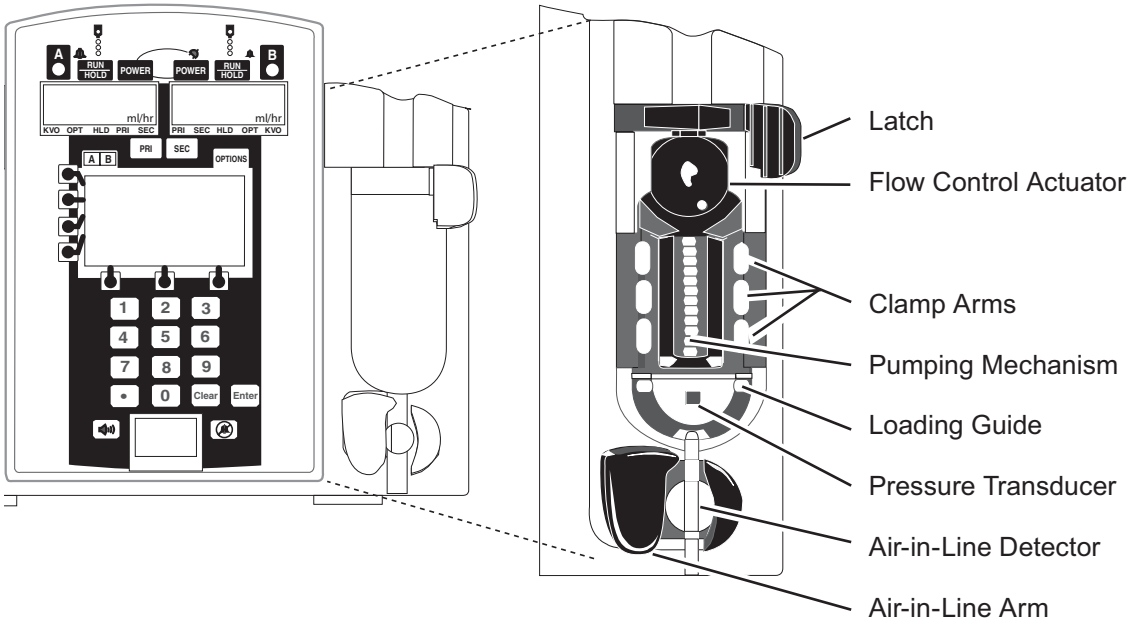
CLEAR Key: Clears selected numeric value.

Audio Volume Key: Sets audio volume for alarms, alerts and KVO tone. Press key to adjust volume.

Numeric Keypad: Enters/changes values.

Operating Features, Controls, Indicators (Continued)





Displays

Main Display

The Main Display is backlit for easy viewing. The backlight dims when operating on battery power as an energy-saving feature. Pressing any key automatically turns the backlight up again.

CAUTION

Appearance of lines and/or dots that remain on constantly when the instrument is powered on may indicate improper functioning of the Main Display. Although the instrument is functioning properly, return it to qualified service personnel.

Rate Display

LED rate display is easily viewed from a distance.

Rate Display

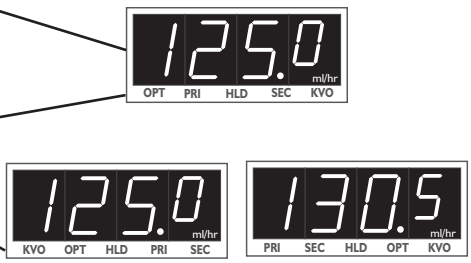
Indicates current infusion rate(s) in mL/h. Flashes to indicate hold or alarm condition, and when in KVO mode.

Model 7130/7131 Status bar

Indicates which mode instrument is in: Optional Modes, Primary, Hold, Secondary, or KVO.

Model 7230/7231 Status bar

Indicates which mode each channel is in: KVO, Optional Modes, Hold, Primary, or Secondary.



Displays (Continued)

Lower Display

The lower LCD display is backlit for easy viewing. The display dims when operating on battery power, as an energy-saving feature.

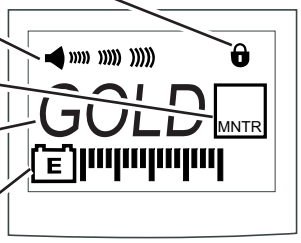
Panel Lock Indicator
Displayed if panel lock is on.

Audio Volume Indicator
Indicates audio volume for alarms and alerts.

Computer Mode Indicator
Displayed if instrument is in computer monitor mode.

Instrument ID Label
Characters are entered to identify selected Profile or configuration, ownership, location, etc.

Battery Power Gauge
Indicates approximate battery time remaining under current infusing conditions.



Feature Definitions

Bolus Dose — Continuous infusions within Dose Rate Calculator mode may include Bolus dosing. Enabling this mode allows a bolus infusion to be programmed using either Drug Library or Drug? NO DOSE LIMIT option. Bolus infusion can be programmed with or without a continuous infusion to follow bolus.

Data Set — Created using Editor Software authoring tool and then transferred to SE Pump. A Data Set reflects facility's best-practice guidelines for IV Drug administration and includes: Profile Drug Libraries, Profile Fluid Libraries, Clinical Advisories and instrument configurations.

Drug Library — Allows flow rate or drug dose rate to be entered for a continuous infusion. System then calculates alternate parameter based on drug concentration and weight if used.

Guardrails® Suite MX — Designed to help prevent programming errors by:

- Customizing instrument configurable settings to meet need of selected hospital/facility area/unit (profile).
- Comparing user programming with hospital-defined best-practice guidelines.
- Providing a prompt if an out-of-limits entry is made.

Features and Displays (Continued)

Feature Definitions (Continued)

IV Fluid

Allows rate and volume to be entered for an infusion that is delivered in mL/h, providing a prompt if a rate is entered that is outside facility's best-practice guidelines.

Profile

A unique set of system configuration settings and best-practice guidelines for a specific patient population or patient type, and can consist of following components:

- Instrument configuration settings.
- A Drug Library, which includes Guardrails® drug names, standard concentrations, dosing units, duration limits, and optional associated Clinical Advisories for continuous, intermittent and bolus dose infusions.
- An IV Fluid library, an optional library consisting of IV fluids (for example, TPN) and limits around rate of delivery.

Profile settings are established by facility's own multi-disciplinary team prior to system implementation. Profile parameters are used to create a Data Set, which is then transferred to SE Pump.

Configurable Settings

With the Profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best-practice Data Set must be uploaded to enable the Profiles feature.

If the Profiles feature is not enabled (off) or if no Data Set is loaded, the configurations options are set in the configuration mode by qualified service personnel. If the configuration settings need to be changed from the factory default settings, reference the Technical Service Manual or contact Cardinal Health Technical Support for technical, troubleshooting, and preventive maintenance information.

Configurable Settings (Continued)

Configurable Option Definitions - General

Air in Line:

Air in Line Threshold (microliters) — Sets upper limit for a single bolus of air to pass without alarm. In other words, it is amount of air allowed to pass through air-in-line detector before an air-in-line alarm sounds. One of 4 different air-in-line detection settings can be selected: 50, 100, 200, 500 mcL.

AIL Accumulator — Detects presence of multiple air bubbles that are too small to be detected by single bolus AIL detection limit. Accumulator feature, when enabled, looks for 10-15% of downstream fluid path to be air before giving an ACCUMULATED AIR IN LINE alarm. Volume of air that trips accumulated air detection alarm varies based on current setting for single air bolus.

AIL Reset — Allows clinician to respond to an air-in-line alarm, assess its clinical significance, and choose whether or not to continue infusion without removing air. Reset feature allows only current bubble to proceed without tripping alarm.

Audio:

Transition Tone (Secondary to Primary) — Provides an audible tone when secondary VTBI reaches zero, to indicate infusion has transitioned to primary rate.

Volume — Provides clinician with ability to adjust audio volume for alarms, alerts and KVO tone to either High, Medium, or Low if all audio volume levels are enabled. Audio volume indicator in lower LCD display indicates audio volume selected. Instrument can be configured to enable only Medium and High, or only High audio volume levels if desired.

Configuration Name

Allows a 4-digit instrument ID label to appear in lower LCD display, identifying patient care profile.

Configurable Option Definitions - General (Continued)

Dynamic Monitoring:

Auto Restart Plus — Part of the Dynamic Monitoring system and designed to help minimize nuisance "occlusion downstream" alarms. It allows instrument to automatically continue an infusion following detection of a downstream occlusion if downstream pressure falls to an acceptable level within a 40-second Checking Line period. May be set to off (0 restarts) or to allow from 1 – 9 Checking Line restarts. If allowable number of restarts is exceeded, or when resistance or pressure conditions indicate an occlusion, an occlusion downstream alarm occurs.

Monitoring Options — Dynamic monitoring provides clinician ability to select one of following monitoring modes: Resistance mode, High Resistance mode or Pressure mode. All of these modes offer an optional Auto-Restart Plus feature and optional trend graph display.

Trends — Provides ability to display downstream pressure or flow resistance over time. Trend graphs of 15 minutes, 1 hour, 4 hours and 12 hours are available during normal operation. When Trends is enabled, if instrument is operating in pressure mode, a pressure trend graph is available, and when it is operating in resistance mode, a resistance trend graph is available.

Dynamic Monitoring - Pressure:

Adjustable pressure is designed to monitor IV line/site pressure and provide user-adjustable pressure alarm limits. It is used for Precision Flow mode or for high resistance systems; such as, infusion through transducers, into dialysis systems and through highest resistance catheters. Pressure mode may be configured to operate with a fixed pressure alarm limit threshold so that it is not user-adjustable.

Manual Pressure Baseline — Provides a real-time bar graph and numeric display of line pressure.

Pressure Alarm — When Pressure Display is enabled, Pressure Alarm may be set to Adjustable Pressure mode or Fixed Pressure mode.

Pressure Display — In Adjustable Pressure monitoring mode, pressure alarm limit may be varied by from 25 mmHg to maximum configured pressure limit in 25 mmHg increments. Pressure Display indicates current pressure limit and provides ability to adjust limit by pressing "increase" or "decrease" arrows.

In Fixed Pressure mode, pressure limit of 600 mmHg displays, with no means of adjusting it. When Pressure Display is disabled, instrument automatically defaults to Fixed Pressure mode.

Configurable Option Definitions - General (Continued)

Dynamic Monitoring - Pressure:
(Continued)

Pressure Limit, Initial — This is default pressure alarm limit that is automatically set when instrument is powered on and a new profile is selected or **New Patient? - Yes** is selected. Alarm level must be less than or equal to maximum pressure limit.

Pressure Limit, Maximum — In Adjustable Pressure monitoring mode, pressure alarm limit may be varied by from 25 mmHg to this maximum configured pressure limit in 25 mmHg increments. A value that exceeds this pressure limit cannot be selected.

Dynamic Monitoring - Resistance:

Resistance Monitoring eliminates the impact of patient elevation and flow rate, to provide the most direct assessment of patency. It is designed to monitor IV line/site resistance providing optimum sensitivity for most IV applications. High Resistance is designed to monitor IV line/site resistance with optimum sensitivity where higher resistance catheters are used.

Default Resistance Alert — Default resistance alert level that is automatically set when instrument is powered on and a new profile is selected or **New Patient? - Yes** is selected. Resistance Alert Marker can be adjusted up or down from this default setting, as needed.

Resistance Alert — Provides an early warning of increasing flow resistance. When enabled, Resistance Alert marker can be set by from 0% to 100% of scale in 5% increments (Resistance Display must also be enabled). To optimize alert feature, it is advisable to set alert level 20-30% higher than initial displayed resistance, which should be read approximately 2 minutes after starting an infusion.

Resistance Display — When enabled provides a bar graph on Main Display to indicate current % resistance on a scale of 0 – 100%. When disabled, resistance alert feature is unavailable.

Resistance Pressure Setting — Provides an “Occlusion Downstream” alarm when measured pressure reaches Resistance Pressure limit while operating in Resistance Mode. This threshold may be set from 1 to 600 mmHg in 1 mmHg increments. In other words, while operating in Resistance mode or High Resistance mode, an “Occlusion Downstream” condition can be detected in 2 ways; measured resistance reaches 100% of scale or configured Resistance Pressure Setting is exceeded.

KVO Rate

KVO (keep vein open) mode automatically occurs when primary VTBI has counted down to 0.0 mL. Channel switches to preset KVO rate or remains at current rate, whichever is less. KVO rate may be set to a value between 0.1 and 20 mL/h in 0.1 mL/h increments. KVO rate is not adjustable by the clinician.

Optional Modes:

Optional modes include Loading Dose, Dose Rate Calculator, Multi-Step, and Multi-Dose. Each of these can be either enabled or disabled. When disabled, they will not appear on the Options menu and cannot be accessed by the clinician.

Dose Rate Calculator

Allows clinician to enter either flow rate or drug dose rate for a continuous infusion. System then calculates alternate parameter based on drug concentration and weight if used.

For an intermittent infusion, system calculates total dose based on drug amount and patient weight (kg) or BSA (m^2) if used. Next, clinician enters either volume and time to calculate rate, or rate and volume to calculate time.

Dose rate calculator must be enabled in order to access Bolus Dose feature and Drug Library.

Loading Dose

Allows clinician to set up an initial infusion rate for a specific volume, to be followed automatically by a maintenance rate (primary settings) from same container. This is useful for delivering fluid challenges. Limits do not apply when using Loading Dose feature. To deliver a loading dose of a medication selected from Drug Library, Bolus Dose feature may be used.

Multi-Dose

Allows 1 - 24 doses to be programmed at equally spaced intervals on same instrument over a 24-hour period. This mode allows delivery of multiple, equal doses from same IV container at regularly scheduled intervals. Limits do not apply when using Multi-Dose feature. Within this mode, a delayed start option allows instrument to be programmed to delay infusion start for up to 8 hours.

Multi-Dose Alert

When enabled, this feature alerts clinician of completion of each dose delivered during a Multi-Dose program.

Configurable Settings (Continued)

Configurable Option Definitions - General (Continued)

Optional Modes: (Continued)

Multi-Step

Allows a sequential drug delivery program (up to 9 steps) to be set delivering volumes of fluid at different rates at each step. This allows instrument parameters to be set up once and deliver a step profile, eliminating need to change rate and VTBI after each step of infusion. Infusion may be programmed in rate/volume or volume/time. Limits do not apply when using Multi-Step feature.

Rate, Maximum

Maximum infusion rate may be set to a value from 0.1 to 999.9 mL/h in 0.1 mL/h increments.

Configurable Option Definitions - Guardrails® Suite MX

BSA, Maximum

Sets maximum patient body surface area for each profile. May be set to a value from 0.05 to 3 m^2 (meters squared) in 0.01 m^2 increments.

Dose Checking Mode

Dose Checking (limit checking) has 2 selectable options:

- Always checking option causes a Guardrails® alert to occur each time a dose limit is exceeded. If limit is overridden, drug label displays an indicator (↑↑↑ or ↓↓↓ arrows) that infusion is beyond current Soft Limit.
- Smart option causes an initial Guardrails® alert to occur when a dose limit is exceeded. Subsequent programming beyond dose limit does not cause an alert to display. If limit is overridden, drug label displays an indicator (↑↑↑ or ↓↓↓ arrows) that infusion is beyond current Soft Limit

Weight, Maximum

Sets maximum patient weight (kg) for each profile. May be set to a value from 0 to 4534 kg in 1 kg increments.

Configurable Settings (Continued)

Configurable Options

Feature	Options	Default
Air-in-Line:		
Air-in-Line Accumulator	On/Off	On
Air-in-Line Threshold	50,100,200, or 500 mcL	100 mcL
Air-in-Line Reset	On/Off	Off
Audio:		
Transition Tone	On/Off	On
Volumes	Low/Med/Hi Med/Hi Hi	Low/Med/Hi
Configuration Name	4 alphanumeric characters	GOLD
BSA, Maximum*	0.05 - 3	3
Dynamic Monitoring:		
Auto Restart Plus	0 (Off) /1 to 9	3
Monitoring Options	Resistance/High Resistance/Pressure	Pressure
Trends	On/Off	On
Pressure:		
Manual Pressure Baseline	On/Off	On
Pressure Alarm	Adjustable/Fixed	Adjustable
Pressure Display	On/Off	On
Pressure Limit, Initial (Configuration Mode: Def Alarm)	25-600 mmHg	600 mmHg
Pressure Limit, Maximum	25-600 mmHg/600 mmHg	600 mmHg
Resistance:		
Default Resistance Alert	0-100%	100%
Resistance Alert	On/Off	On
Resistance Display	On/Off	On
Resistance Pressure Setting	1-600 mmHg	600 mmHg
Dose Checking Mode*	Smart/Always	Always
KVO Rate	0.1 - 20 mL/h	5.0 mL/h
Optional Modes:		
Bolus	On/Off	Off
Dose Rate Calculator	On/Off	Off
Loading Dose	On/Off	On
Multi-Dose	On/Off	Off
Multi Dose Alert	On/Off	Off
Multi-Step	On/Off	Off
Panel Lock	On/Off	On
Rate, Maximum	0.1 - 999.9 mL/h	999.9 mL/h
Weight, Maximum*	0.001 - 4,534 kg	4,534 kg

* These features are configured only within a hospital-defined best-practice Data Set.

Configurable Settings (Continued)

System Configurable Options

The following features can be customized by qualified service personnel in the Configuration or Diagnostic Modes.

Feature	Options	Default
Computer Link:		
Baud Rate	300/600/1200/1800/2400/4800/9600	9600
Mode	Monitor/Off, Off	Off
Parity	Even/Odd/None	None
Instrument ID*	9 digits	000000000
Maintenance:*		
Maintenance Interval	1-52 wks	52 wks
Maintenance Reminder	On/Off	On
Pressure Sensor*		
Self Check Interval	1-52 wks	12 wks
Profiles	On/Off	Off
Regional Settings	Region: North America, European Language: English	North America English **
VTBI	On/Off (Flow Sensor use)	On

* These features are configured in the Diagnostics Mode.

** Instruments manufactured for sale in Europe will be set, at the factory, to European English. If a new logic board is installed or the instrument is set to factory defaults, the instrument defaults to North America English. If the language needs to be reset, contact qualified service personnel.

Specifications

Administration Sets: Use only administration sets for SE Pump.

Alarms:

- Accumulated Air In Line
- Air In Line
- Battery Depleted
- Channel Malfunction
- Computer Link Failure
- Flow Sensor Unplugged
- Hold Time Exceeded
- Instrument Malfunction
- Key Stuck
- Latch Open
- No Upstream Flow Detected
- Occlusion Downstream
- Occlusion Upstream
- Primary Flow Detected During Secondary
- Set Out
- Set Up Time Exceeded

Specifications (Continued)

Battery: Rechargeable nickel-cadmium. A single channel instrument operates for 4 hours nominal and a dual channel instrument operates for 3 hours nominal, under following conditions:

- new, fully charged battery
- ambient room temperature, 73±7°F (23±4°C)
- resistance monitoring modes
- rate: 100 mL/h on a single channel instrument and 50 mL/h on each channel of a dual channel instrument

Battery run time is affected by operating mode, rate, monitoring options and back pressure (see "General Information", “Battery Management System”).

Case: Impact and flame resistant plastic.

Critical Volume: Maximum incremental volume in case of single point failure does not exceed 1.0 mL at 999.9 mL/h.

Dimensions: (Nominal)

	7130/7131	7230/7231
Depth*	5.0 in/12.7 cm	5.0 in/12.7 cm
Height	8.6 in/21.8 cm	8.6 in/21.8 cm
Power Cord	10 ft/3 m	10 ft/3 m
Weight**	6.6 lb/3.0 kg	8.4 lb/3.8 kg
Width	7.6 in/19.3 cm	10.7 in/26.7 cm

* Without pole clamp. ** Without power cord.

Downstream Occlusion: ①

Time to Alarm

Time to Detect Downstream Occlusion (minutes)		Monitoring Options			
		Pressure		Resistance and High Resistance	
Threshold Settings		25 mmHg	600 mmHg	100% 25 mmHg	100% 600 mmHg
1 mL/h	Maximum	2	75	2	7
	Typical	0.6	30	0.6	4
25 mL/h	Maximum	1	25	1	3
	Typical	0.1	1	0.1	1

When occlusion alarm pressure limit is set to maximum threshold setting, maximum infusion pressure generated into a hard occlusion at 25 mL/h is 11.6±3.9 psi.

Specifications (Continued)

Downstream Occlusion: ① (Continued)

Bolus Volume

Bolus Volume Released Upon Correcting Downstream Occlusion (mL)		Monitoring Options			
		Pressure		Resistance and High Resistance	
Threshold Settings		25 mmHg	600 mmHg	100% 25 mmHg	100% 600 mmHg
1 mL/h	Maximum	0.5	0.5	0.5	0.5
	Typical	<0.1	0.3	<0.1	<0.1
25 mL/h	Maximum	0.5	0.5	0.5	0.5
	Typical	<0.1	0.3	<0.1	0.3

Testing performed using Model 72003 administration set, at 68±8°F (20±4°C).

Environmental Conditions:	Operating	Storage
Atmospheric Pressure	700 to 1060 hPa	500 to 1060 hPa
Relative Humidity	20 to 90% Noncondensing	5 to 95% Noncondensing
Temperature Range	41 to 104°F (5 to 40°C)	-40 to 140°F (-40 to 60°C)

Flow Rate Range: 0.1 to 600.0 mL/h in 0.1 mL/h increments (secondary mode)
0.1 to 999.9 mL/h in 0.1 mL/h increments (all other modes)

Ground Current Leakage: Electrical leakage current, enclosure: <100 microamperes
Electrical leakage current, patient: <10 microamperes

KVO Flow Range: 0.1 to 20.0 mL/h in 0.1 mL/h increments

Mode of Operation: Continuous

Power Requirements: 100-240 V~, 50/60 HZ (72 VA MAX), 3-wire grounded system
Class 1 with Internal Power Source

Specifications (Continued)

Rate Accuracy:

For rates greater than 1 mL/h, up to 999.9 mL/h: ±5%, 95% of time with 95% confidence, under conditions listed below.

For rates equal to or less than 1 mL/h: ±6.5%, 95% of time with 95% confidence, under conditions listed below.

Rate Accuracy Test Conditions:

Infusion rate range: 0.1 to 999.9 mL/h
Head height: 24 ±1 in. (61±2.5 cm)
Test solution: distilled water
Environment temperature: 68±8°F (20±4°C)
Back pressure: 0 psi
Needle: 18 gauge
Set Model: 72003
Minimum collection volume: 6 mL

CAUTION

Variations of head height, back pressure, time, monitoring mode option, pump tilt or any combination of these **may affect rate accuracy**. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure may also be affected by catheter type. See "Trumpet and Start-up Curves" for data on how certain factors influence rate accuracy.

Volume Infused Range: 0.0 to 9999.9 mL in 0.1 mL increments

VTBI Range: 0.1 to 9999.9 mL in 0.1 mL increments (Basic Infusion, Drug Library Primary Infusion, IV Fluid Infusion and Multi-Step mode); 0.1 to 999.9 mL in 0.1 mL increments (all other modes)

NOTE:

① Time to Occlusion and Bolus Volume data tested to standards defined in AAMI ID26:1998, Section 51.101 b.

Symbols and Terms

Alarm indicator.

Caution: Refer to accompanying documentation.

Audio volume.

Approximate battery time remaining under current infusing conditions. Battery gauge does not represent battery time remaining when instrument is turned off.

Conformité Européenne [CE - Marking] notified body “0086”: British Standards Institution.

Electrical shock protection rating: Type CF ①

Type CF defibrillation-proof equipment. ①

Explosion risk if used in presence of flammable anesthetics.

Flow sensor receptacle (optional), channel A.

Flow sensor receptacle (optional), channel B.

Infusing indicator.

IPX1 Indicates degree of protection, liquid ingress.

Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture.

Nurse Call (optional for 7130/7230).

Consult operating instructions.

Panel lock.

Symbols and Terms (Continued)

Green = instrument plugged into AC power and battery being charged.
Flashing amber = instrument running on battery power and battery being depleted.

RS-232 connector.

Silence mode.

Split screen (dual channel instrument only).

Transition Tone — A brief tone during transition from one mode to another.

Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards (CSA C22.2 No. 125).

Single-Use. Do not re-use.

DEHP in fluid pathway.

No DEHP in fluid pathway.

Product contains latex.

Product is latex free.

Drops per milliliter specification for product is identified on drop symbol.

Product incorporates Needle-Free Valve ports and should not be accessed by a needle.

Approximate set priming volume.

Expiration date for product is identified near hour glass symbol.

Do not use if package is damaged.

Symbols and Terms (Continued)

NOTE:

① Depending on manufacturing and distribution timing, the SE Pump may bear either the CF or CF Defibrillator-Proof symbol on the main rating label. The SE Pump has been tested and complies with IEC 60601-1 Amendment 2, Clause 17 (h) for Defibrillator-Proof Equipment.

cm	centimeter
day	day (d)
gm	gram (g)
h	hour
HLD	infusion in “hold” mode
in	inch
kg	kilogram
KVO	“keep vein open” infusion rate mode
lb	pound
mcg	microgram (µg)
mcL	microliter (µL)
mEq	milliequivalent
mg	milligram
min	minute
mL	milliliter
mmol	millimole
mUn	milliunit
nan	nanogram (ng)
OPT	optional mode
PRI	primary infusion mode
rev	revolution (r)
SEC	secondary infusion mode
Un	unit
VI	volume infused
VTBI	volume to be infused
wks	weeks

Trumpet and Start-Up Curves

DESCRIPTION AND EXPLANATION OF TRUMPET AND START-UP CURVES

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual administration sets cause short-term fluctuations in rate accuracy. The following graphs show typical performance of the system for both Pressure and Resistance modes in two ways:

- Accuracy during various time periods over which fluid delivery is measured (trumpet curves).
- Delay in onset of fluid flow when infusion commences (start-up curves).

Product operation is not affected by the selection of Resistance or High Resistance at 0.1, 1.0, and 25 mL/h; therefore, High Resistance graphs are not included.

Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or “observation windows”, not continuous data versus operating time. Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect, as represented by the “mouth” of the trumpet. Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

The start-up curves represent continuous flow rate versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

FLOW CHARACTERISTICS UNDER VARYING DELIVERY CONDITIONS

Effects of Pressure Variations

Under conditions of +100 mmHg pressure, the SE Pump typically exhibits a long-term accuracy offset of approximately -1.4% from mean values.

Under conditions of +300 mmHg pressure, the SE Pump typically exhibits a long-term accuracy offset of approximately -1.5% from mean values.

Under conditions of -100 mmHg pressure, the SE Pump typically exhibits a long-term accuracy offset of approximately -0.8% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short–term variations result under these pressure conditions.

Effects of Negative Solution Container Heights

With a negative head height of -0.5 meters, the SE Pump typically exhibits a long–term accuracy offset of approximately -5.8% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short–term variations result under negative head height conditions.

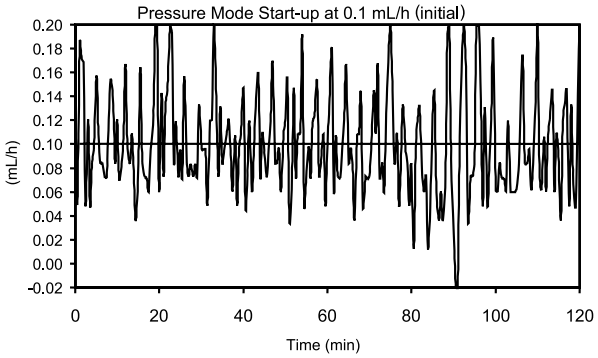
Effects of Rate

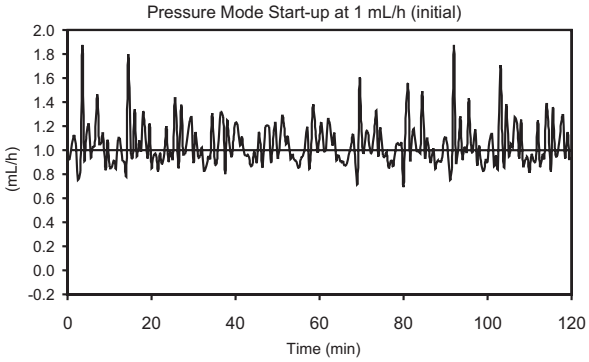
For applications where flow uniformity is a concern, use of the Pressure Mode at rates of 1.0 mL/h or above is recommended.

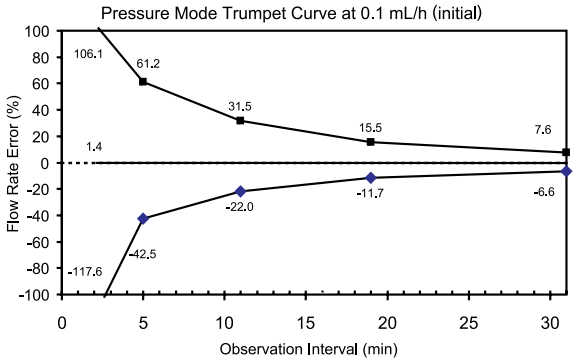
NOTE: Tests conducted in accordance with IEC 60601–2–24, “Particular requirements for safety of infusion pumps and controllers” and AAMI ID26–1998 “Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers”, using a Model 72003 Administration Set (includes Flow Regulator).

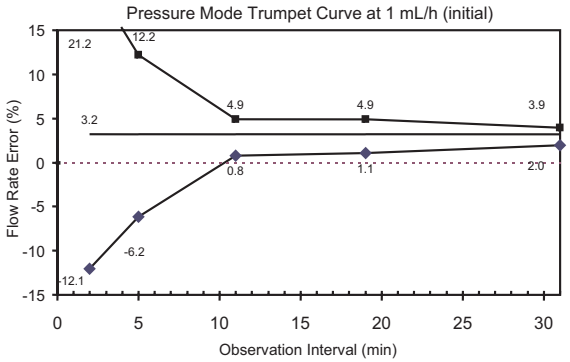
Trumpet and Start-Up Curves (Continued)

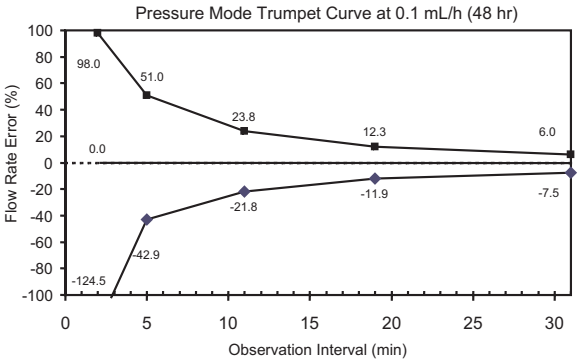
Pressure Mode

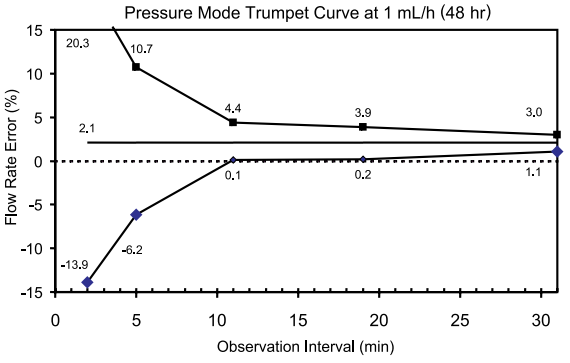












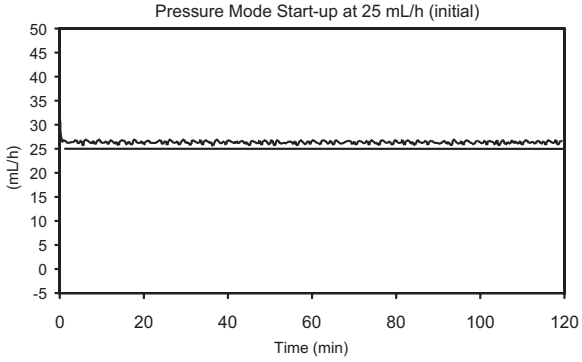
NOTE: The plot range has been increased to ±100%, to allow visualization of the graph.

Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

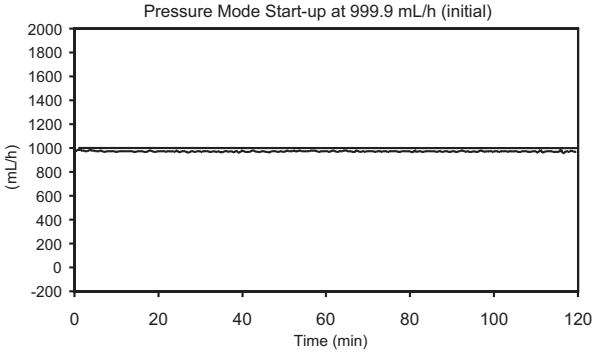
Trumpet and Start-Up Curves (Continued)

Pressure Mode (Continued)

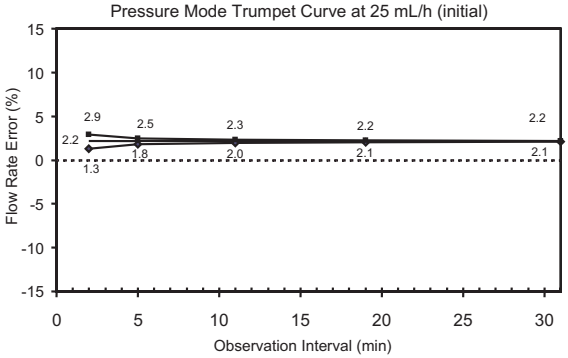
Pressure Mode Start-up at 25 mL/h (initial)



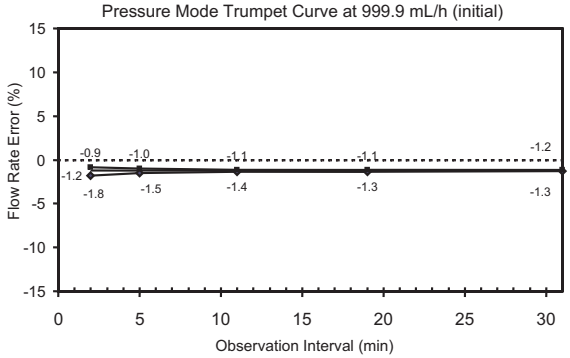
Pressure Mode Start-up at 999.9 mL/h (initial)



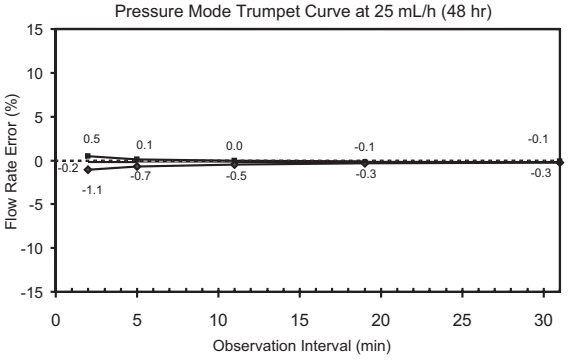
Pressure Mode Trumpet Curve at 25 mL/h (initial)



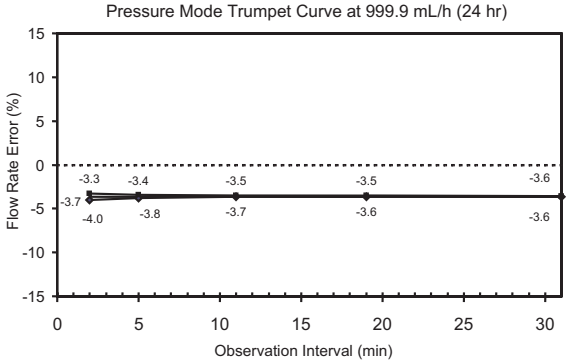
Pressure Mode Trumpet Curve at 999.9 mL/h (initial)



Pressure Mode Trumpet Curve at 25 mL/h (48 hr)



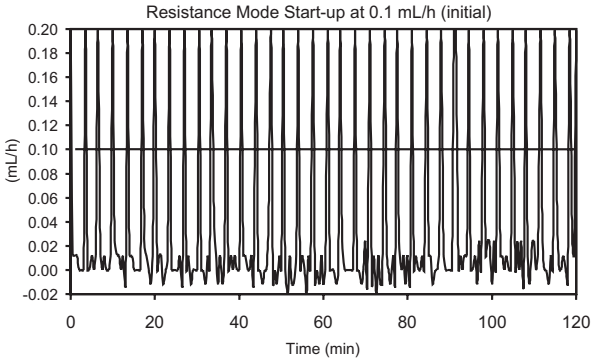
Pressure Mode Trumpet Curve at 999.9 mL/h (24 hr)

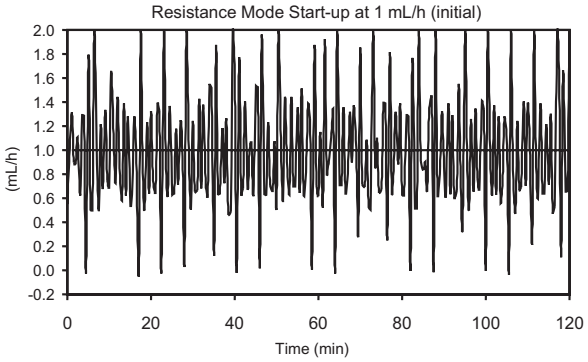


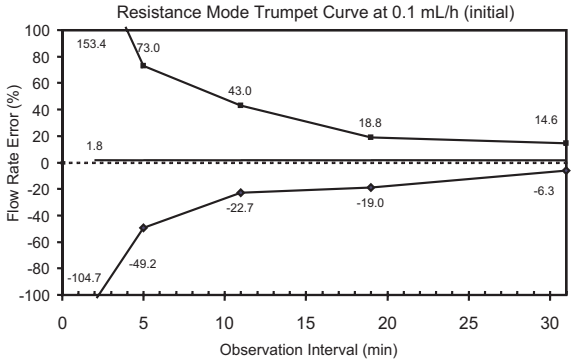
Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

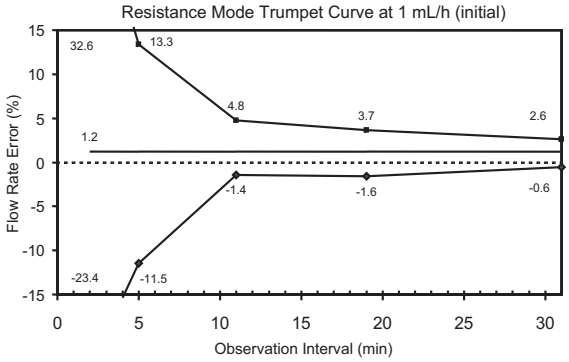
Trumpet and Start-Up Curves (Continued)

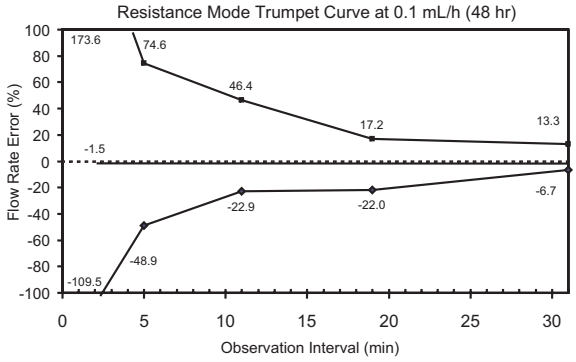
Resistance Mode

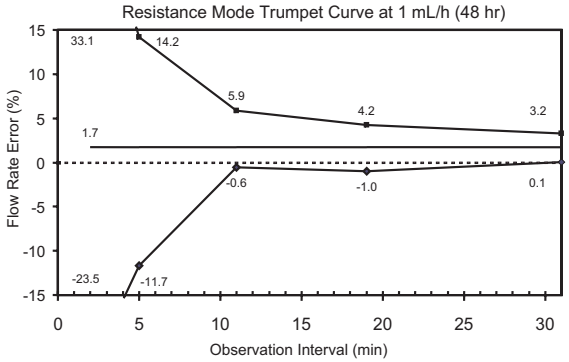












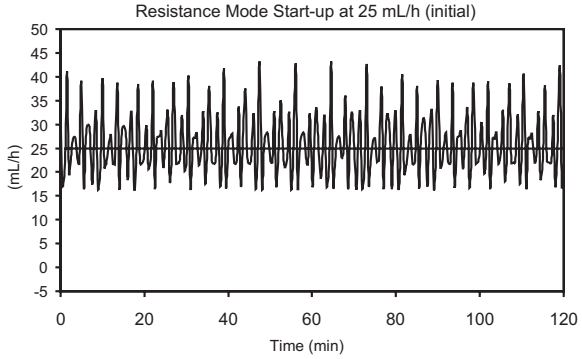
NOTE: The plot range has been increased to ±100%, to allow visualization of the graph.

Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

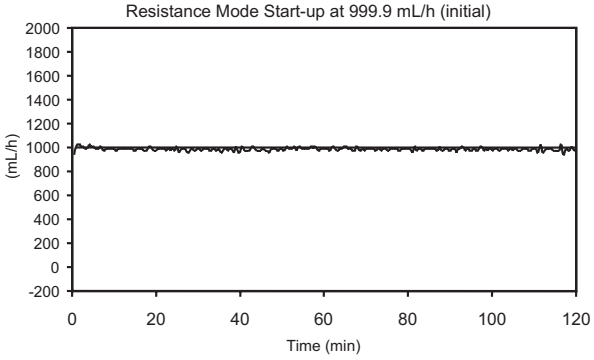
Trumpet and Start-Up Curves (Continued)

Resistance Mode (Continued)

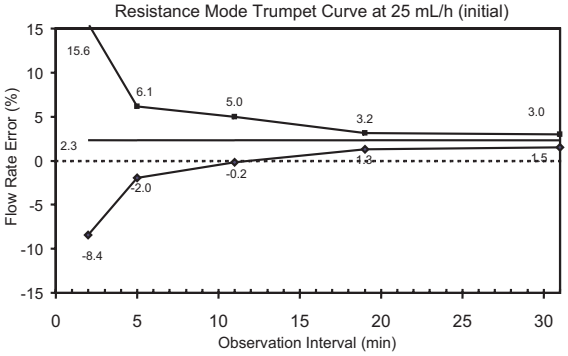
Resistance Mode Start-up at 25 mL/h (initial)



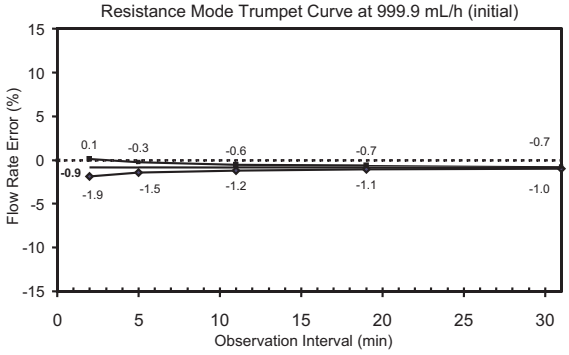
Resistance Mode Start-up at 999.9 mL/h (initial)



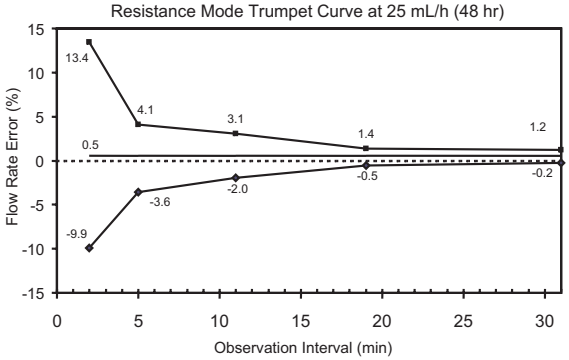
Resistance Mode Trumpet Curve at 25 mL/h (initial)



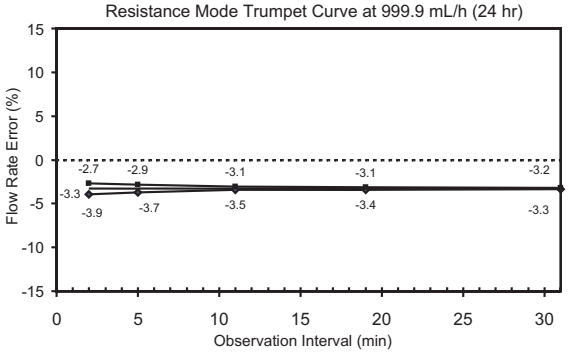
Resistance Mode Trumpet Curve at 999.9 mL/h (initial)



Resistance Mode Trumpet Curve at 25 mL/h (48 hr)



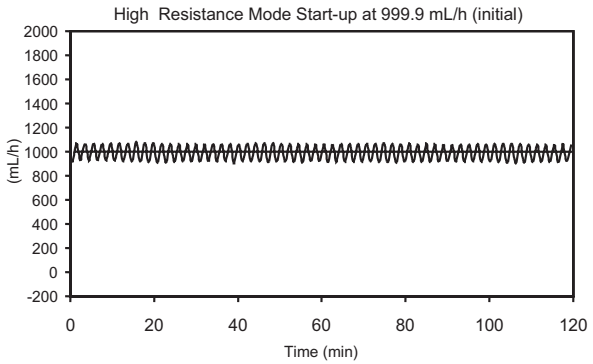
Resistance Mode Trumpet Curve at 999.9 mL/h (24 hr)

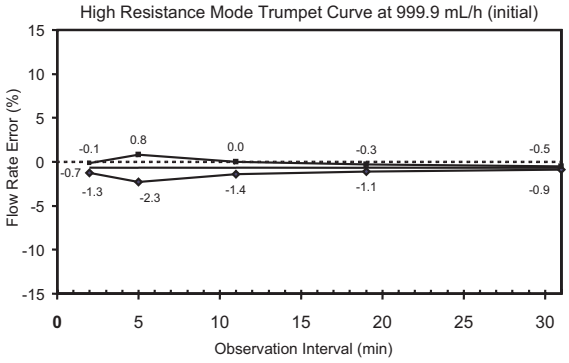


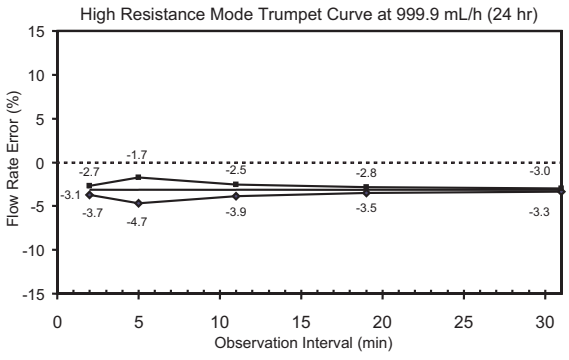
Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

Trumpet and Start-Up Curves (Continued)

High Resistance Mode







Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

General

The SE Pump Technical Service Manual is available from Cardinal Health. It includes routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information, to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel.

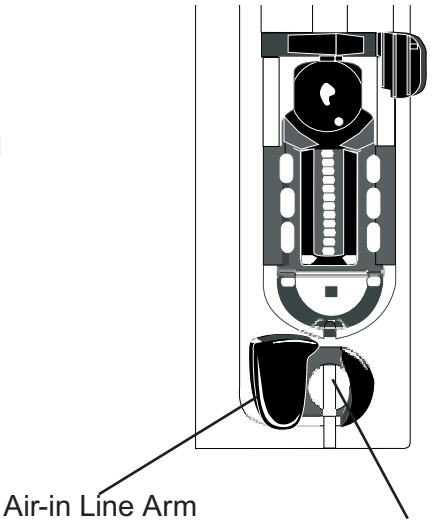
Artifacts: It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportional to the infusion device flow rate. When an ECG monitoring system is not functioning under optimal conditions, these currents may appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Reference the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

Air In Line Assembly

The Air-in-Line Detection System provides clinicians the ability to detect inappropriate amounts of air in the IV line. The instrument is configurable to allow single bubble and accumulated air detection. Accumulated air detection is based on measurement of the average percentage produced by small air bubbles passing the detector. ①

Air is detected by an emitter (Air-in-Line arm) which rotates into position as the latch is closed. A receiver (Air-in-Line Detector), opposite the arm and just below the Pumping Mechanism, sends the Air-in-Line information to the main processor.

Qualified biomedical personnel may configure 1 of 4 possible sensitivity levels. The instrument is also configurable to permit the operator to clear (reset) any air registered in the instrument's memory.



Air In Line Assembly (Continued)

NOTE:

① Ensure that the tubing is properly inserted into the air detector to avoid false alarms. The tubing may be reshaped to ensure optimum contact with the sensors. Periodically clean the Air-in-Line Detector to ensure a clear signal can be received (see "Cleaning").

Single or Accumulated Air Bubble Detection (NO Reset Feature)

1. To place channel on hold, press **hold** soft key.
2. Remove air per hospital protocol. ①
3. To resume infusion, reinstall set and then press **RUN/ HOLD** key.

   If air volume is clinically insignificant, press **reset** soft key or **RUN/ HOLD** key, followed by **run** soft key or **RUN/ HOLD** key to resume infusion.

   - Subsequent air bubbles trigger alarm.

NOTE:

① Opening the latch or turning the channel off clears air memory.

Alarms, Alerts, Prompts

There are 3 types of displayed messages listed on the following pages with a probable cause and suggested remedy next to each one. Use this section in conjunction with the appropriate clinical practice of hospital procedure. Additional information can be found in other sections of this DFU (see "Table of Contents"). Use this section in conjunction with the appropriate clinical practice or hospital procedure.①

ALARM: instrument or channel problem.

- infusion stops
- alarm bell icon illuminates
- alarm tone sounds
- rate LED display flashes
- message appears in Main Display when channel is selected

ALERT: may indicate a change in infusion status.

- channel continues to operate
- alert tone sounds
- message appears in Main Display

PROMPT: infusion status not changed.

Startup procedures were not completed or an invalid key was pressed.

NOTE:

① When using the dual channel instrument, some messages also display Channel A or Channel B, to indicate which channel is affected. Always verify the channel is selected before making any changes.

Alarms, Alerts, Prompts (Continued)

Alarms

Alarm	Meaning	Response
ACCUMULATED AIR IN LINE	Air detector has detected multiple small bubbles.	Press **hold** soft key. Open latch to remove set. Clear air per hospital protocol. Reinstall set. Press **Run/Hold** to resume infusion. **OR** If reset key is active and air bubbles are clinically insignificant, press **reset** soft key and then press **run** soft key to resume infusion. Ensure air-in-line sensors are thoroughly cleaned.
AIR IN LINE	Air detector has detected an air bubble larger than configured threshold tolerance.	Press **hold** soft key. Open latch to remove set. Clear air per hospital protocol. Reinstall set. Press **RUN/HOLD** to resume infusion. **OR** If reset key is active and air bubbles are clinically insignificant, press **reset** soft key and then press **run** soft key to resume infusion. At flow rates of 1.0 mL/h and below, verify upstream fluid path is unobstructed. Ensure air-in-line sensors are thoroughly cleaned.
BATTERY DEPLETED (Plug In)	Battery is too low to operate instrument.	Plug power cord into an AC outlet immediately. Press **run** soft key or **RUN/HOLD** to resume infusion.

Alarms, Alerts, Prompts (Continued)

Alarms (Continued)

Alarm	Meaning	Response
CHANNEL MALFUNCTION Dual channel instrument only.	Channel malfunction.	Turn channel off and then on. If problem persists, do not use channel. Contact qualified service personnel.
COMPUTER LINK FAILURE	RS-232 connection to computer was disrupted. Computer Link feature is in monitor mode.	Check RS-232 connections. Clearing this alarm automatically puts instrument in monitor mode. Reestablish infusion.
FLOW SENSOR UNPLUGGED	Flow sensor is unplugged from back of instrument.	Plug flow sensor into flow sensor receptacle.
HOLD TIME EXCEEDED	Channel has been on hold for 2 minutes and no keys have been pressed (on either channel if dual channel).	Press **hold** soft key to return to hold mode.
INSTRUMENT MALFUNCTION	Instrument malfunction. For a dual channel instrument, neither channel is functional.	Turn instrument off and then on. If problem persists, do not use instrument. Contact qualified service personnel.
KEY STUCK	A key is stuck or was held down too long.	Release key. Turn instrument off (both channels if dual channel instrument) and then on. If problem persists, do not use instrument. Contact qualified service personnel.
LATCH OPEN	Latch was opened during an infusion.	Check for proper set installation. Close latch fully to the left. Press **run** soft key.

Alarms (Continued)

Alarm	Meaning	Response
NO UPSTREAM FLOW DETECTED	Flow has been obstructed between container and instrument when using a flow sensor.	Check to see if container is empty, flow sensor is mispositioned or clouded, tubing is kinked or air vent is closed. Verify correct set connections and open fluid path. Press **run** soft key to restart infusion. ①
OCCLUSION DOWNSTREAM	Pressure in IV line has exceeded a pressure alarm threshold. OR Resistance has reached 100%.	Check administration set for probable cause (such as kinked tubing, closed stopcock, high resistance catheter). Press **run** soft key to restart infusion.
OCCLUSION UPSTREAM	Flow has been obstructed between fluid container and instrument's pressure sensor.	Check administration set for probable cause (such as kinked tubing, closed clamp). Verify that blue thumb clamp on Flow Regulator has moved to open (up) position. If not, reload set. Press **run** soft key to restart infusion.

NOTE:

① Infusing fluids which form smaller drops through a 60 drops/mL set at high rates may result in a No Upstream Flow Detected alarm. (This is because the small, rapidly falling drops form a continuous stream which does not trigger the flow sensor). In this event, unplug the flow sensor from the instrument.

Alarms, Alerts, Prompts (Continued)

Alarms (Continued)

Alarm	Meaning	Response
PRIMARY FLOW DETECTED DURING SECONDARY	Instrument detected flow from primary container during secondary infusion. **NOTE**: Alarm can only occur when using optional flow sensor.	Verify that flow sensor is on Primary line and that set up is correct.
SET OUT	Set has been removed during an infusion.	Reinstall set. Press **run** soft key to restart infusion
SETUP TIME EXCEEDED	Instrument has been turned on but no keys have been pressed for 10 minutes.	Press **hold** soft key to return to hold mode. Instrument turns off if left in alarm more than 5 minutes. If an audio alarm remains on, turn instrument on and then off.

Alarms, Alerts, Prompts (Continued)

Alerts

Alert	Meaning	Response
Battery Low	Battery has 30 minutes or less of charge remaining.	Plug power cord into an AC outlet as soon as possible.
Checking Line	Flow has been obstructed. Auto Restart Plus feature is on.	Auto Restart Plus feature must be on for downstream occlusion alerts (not required for upstream occlusion alerts). Check administration set for probable cause (such as kinked tubing, clogged filter, etc.).
Complete Entry	**ENTER** was not pressed to accept a new value.	Press **ENTER** to confirm entry or press **CLEAR** twice to return to previous settings.**NOTE:** Channel operates as previously programmed until **ENTER** is pressed.
Resistance Alert	IV line resistance has reached preset alert level. Resistance Alert feature is on.	Check downstream line and site. Raise resistance alert level, if appropriate.

Additional Alerts:

Additional alerts provide notification of program completion and/or transition to another mode: Bolus Dose Complete, Dose Complete (Multi-Dose Mode), Loading Dose Complete, Multi-Step Complete, Secondary Complete, Infusion in KVO or VTBI = 0.)

Alarms, Alerts, Prompts (Continued)

Prompts

Prompt	Meaning	Response
Air In Line	Air detector has detected air prior to starting infusion or is in poor contact with set.	Press **continue** soft key to allow infusion to continue. An alarm occurs if air detector detects an air bubble larger than configured threshold. Verify set is loaded correctly. Prime and reload set or remove air. Reshape tubing to ensure optimum contact with sensor. Ensure air-in-line sensors are thoroughly cleaned.
Dose Out of Range	Calculated dose is outside allowable range.	Verify and reenter settings.
Entry Invalid	An invalid value was entered during programming.	Press **CLEAR** or **0** key to clear entry. Enter appropriate value.
Instrument Self-Check Is Due Please Eject the Set	Instrument/channel has not performed self-check within programmed interval.	If set is loaded: Eject set, wait 5 seconds and then reload set. If no set is loaded: Load set, wait 1 minute and then eject set. Wait 5 seconds and then reload set.
Invalid Entry Rate Out of Range	Instrument has calculated a rate less than 0.1 mL/h.	Verify and reenter settings.
Latch Open	Latch is open (prior to starting an infusion).	Close latch **fully** to left.
Maintenance Reminder	Periodic maintenance interval has elapsed. Maintenance Reminder feature is on.	Notify Biomedical Engineering department. If desired, press **continue** soft key to temporarily bypass reminder.

Alarms, Alerts, Prompts (Continued)

Prompts (Continued)

Prompt	Meaning	Response
Max Rate = XXX.X mL/h (XXX.X represents maximum flow rate configured for instrument or profile.)	An attempt was made to enter a rate greater than maximum configured rate or instrument has calculated a rate greater than maximum configured rate. Default maximum rate is 999.9 mL/h in primary mode, 600 mL/h in secondary mode.	Verify and reenter settings.
New Baseline Set	A new Manual Pressure Baseline was successfully set. Manual Pressure Baseline feature is on.	Baseline remains set until a new manual baseline is set, instrument is turned off or latch is opened.
Occlusion Downstream	A very high pressure exists in fluid line while baseline is being set. Pressure Baseline feature is on.	Remove source of high pressure and repeat setting of pressure baseline.
Ok Entry	Attempt was made to go to another page before pressing **ok** soft key.	Verify all parameters are correct and press **ok** soft key.
Panel Locked	A key was pressed. Panel lock feature is on.	Turn panel lock off to access panel controls. Panel lock key is located behind handle.
Place on Hold to Change	A key was pressed during KVO.	Channel must be on hold to make changes.
Place on Hold to Set Pressure Baseline	SET PRESSURE BASELINE function was selected while running. Pressure Baseline feature is on.	Place instrument on hold before performing manual SET PRESSURE BASELINE operation.
Press and Hold Key to Turn Off	**POWER** was pressed.	Press and hold **POWER** until display turns off.

Alarms, Alerts, Prompts (Continued)

Prompts (Continued)

Prompt	Meaning	Response
Pressure Limit XXX mmHg (XXX represents configured maximum pressure)	An elevated pressure was present in fluid path when pressure baseline was established. This may reduce maximum available pressure range.	Reload administration set and verify no obstruction exists which could cause excess pressure. • If Pressure Baseline feature is on, repeat manual setting of pressure baseline. OTHERWISE • Restarting infusion automatically sets pressure baseline.
Pressure Limit Must Be Less Than or Equal to XXX mmHg (XXX represents configured maximum pressure)	Attempt was made to increase pressure alarm limit to a level higher than configured maximum pressure.	Choose a pressure alarm limit that is less than, or equal to, configured maximum pressure.
Pressure Unstable Cannot Set Baseline	Excessive variation in pressure due to motion, flow from other instruments or blood pressure prevents accurate setting of pressure baseline. Pressure Baseline feature is on.	Reduce or temporarily remove sources of variation while performing manual baseline setting operation.
Program Lost Re-Enter Settings	Instrument detected a memory or power failure. Existing operating parameters were erased.	Press **continue** soft key and reenter all infusion settings. Configurable options are not affected.
Rate Out of Range	Instrument has calculated a rate less than 0.1 mL/h.	Verify and reenter settings.
Set Must Be Loaded	Flow Regulator segment is not loaded in selected channel during a manual pressure baseline setting operation. Pressure Baseline feature is on.	Load Flow Regulator segment in selected channel. Repeat manual pressure baseline setting.

Alarms, Alerts, Prompts (Continued)

Prompts (Continued)

Prompt	Meaning	Response
Set Out	Flow Regulator segment is not installed correctly.	Reinstall Flow Regulator segment.
Set Pressure Baseline	Set Pressure Baseline was selected in options mode.	Press **ok** soft key to set Pressure Baseline or press **return** soft key to go to exit.
Set Pri VTBI	A primary VTBI was not programmed.	Enter a primary VTBI.
Set Pri VTBI > Loading Dose VTBI	Loading Dose VTBI entered is greater than primary VTBI.	Raise primary VTBI or lower Loading Dose VTBI, as appropriate.
Stop Secondary and Infuse Primary?	**Run** soft key was pressed in Primary Mode when a secondary infusion was on hold.	If return to primary parameters is appropriate press **yes** soft key. If continued secondary infusion is appropriate, press **no** soft key.
Stop Timer to Change	An invalid key was pressed while timer was running in Multi-Dose program.	Wait several seconds for popup to finish. Press **stop timer** soft key to make changes.
The Specified VTBI Will Only Deliver a Partial Dose	Secondary VTBI value is significantly less than bag volume programmed on set up page.	Verify parameters are correct. Press **yes** soft key to proceed or **no** soft key to return to programming.
Time Out of Range	Programmed step time exceeds 24 hours and 59 minutes, or is less than 1 minute.	Verify and reenter settings.

Prompts (Continued)

Invalid Keypress During Programming:

The following Prompts may be seen if an invalid key is pressed during programming: Both A and B not Running, Channel Not On, Complete or OK Setup, No Numeric Entries, Select Channel.

Invalid Keypress During Infusion:

During an infusion, if an invalid key is pressed, the following prompts may be seen: Dose Rate Running, Loading Dose Running, Multi-Dose Running, Multi-Step Running, Pri Running, Sec Running, or Timer Running (Multi-Dose program).

Resuming Previous Programming:

When an instrument has been powered off then on again previous parameters may be preserved if Current Profile is accepted and **New Patient? – No** is selected. The following prompts may be seen: Return to Dose Rate?, Return to Loading Dose?, Return to Multi-Dose?, Return to Multi-Step?, or Return to Secondary?.

Inspection Requirements

To ensure the system remains in good operating condition, both regular and preventive maintenance inspections are required.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
INSPECT FOR DAMAGE:	
Case	Each usage
Connector	Each usage
Keypad	Each usage
CLEANING	As required
START UP	Each usage

WARNING

Failure to perform these inspections may result in improper instrument operation.

CAUTIONS

- R**egular and preventive maintenance** inspections should only be performed by qualified service personnel.
- Inspect LCD for anomalies (improperly lit/unlit pixels).

Cleaning

DO NOT use solutions containing phosphoric acid (Foamy Q&A ①), aromatic solvents (naphtha, paint thinner, etc.), chlorinated solvents ① (Trichloroethane, MEK, Toluene, etc.), ammonia, acetone, benzene, xylene or alcohol, other than as specified below.

DO NOT use hard or pointed objects to clean any part of instrument.

DO NOT use pressurized sprays on instrument.

Acceptable cleaning solutions are (use per manufacturers' instructions):

10% bleach solution (1 part bleach to 9 parts water)
Vesphene
Manu-Klenz
Warm water

1. Unplug power cord from AC outlet before cleaning.
2. Verify RS-232 connector is covered. Do not spray fluid directly into any connector.

WARNING

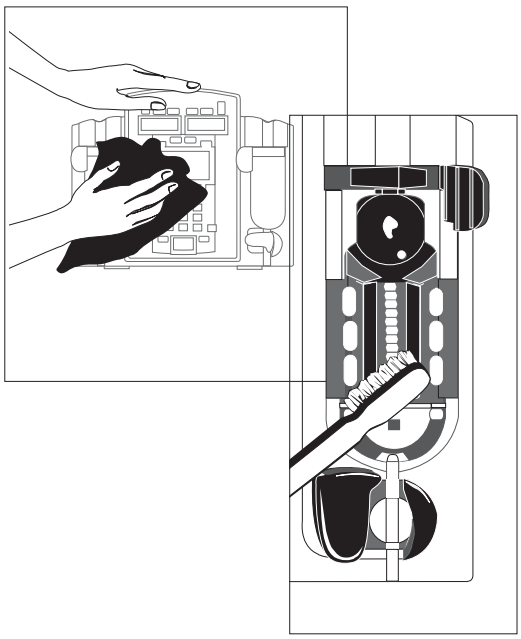
Turn the instrument off and unplug the power cord from AC power **before cleaning**. Do not spray fluids directly onto the instrument. Do not steam autoclave, EtO sterilize, immerse the instrument or allow fluids to enter the instrument case. Failure to follow these instructions may result in an electrical hazard.

CAUTION

The **solutions/solvents** identified as NOT to be used can damage the surfaces of the instrument.

Cleaning (Continued)

3. Use a soft cloth dampened with warm water and a mild, nonabrasive cleaning solution.
   - A soft-bristled brush may be used to clean narrow areas.
   - Use light pressure when cleaning pressure transducer and air-in-line detector areas of pumping channels.
4. Flow sensor should be routinely cleaned by running warm water over it while actuating slider, and then thoroughly dried.



NOTE:

① Excluding 10% bleach solution in water.

Service Information

If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified Cardinal Health service personnel.

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), reference the return authorization information, and return it to the appropriate service or distribution center. Cardinal Health does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

WARNINGS

- The instrument case should only be opened by qualified personnel using **proper grounding techniques**. Prior to performing maintenance, disconnect SE Pump from AC power.
- During servicing, an instrument's **configuration settings** might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the instrument and ensuring the current hospital-approved Data Set is loaded if Guardrails® Suite MX is in use, or that instrument system configuration settings are correct if the Profiles feature is set to OFF.

Technical Support

Technical support, service information, applications, and manuals may be obtained by contacting a Cardinal Health representative.

When submitting any request for service, include:

- model number
- a description of difficulty experienced
- instrument settings
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

WARRANTY

Cardinal Health warrants that:

A. Each new SE Pump is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by Cardinal Health to the original purchaser.

B. The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Cardinal Health to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with Cardinal Health to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at Cardinal Health's expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall Cardinal Health be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any SE Pump product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Cardinal Health shall not be responsible for, any loss or damage arising in connection with the purchase or use of any SE Pump product which has been:

1. repaired by anyone other than an authorized Cardinal Health Service Representative;
2. altered in any way so as to affect, in Cardinal Health's judgment, the product's stability or reliability;
3. subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed; or
4. improperly maintained or used in any manner other than in accordance with the written instructions furnished by Cardinal Health.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Cardinal Health, and Cardinal Health does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Cardinal Health any other liability in connection with the sale or use of SE Pump products.

CARDINAL HEALTH DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

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Compliance

Electromagnetic Environment

This system complies with part 18 of the FCC Rules. Operation is subject to the following 2 conditions:

- This system may not cause harmful interference.
- This system must accept any interference received, including interference that may cause undesired operation.

The digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the radio interference regulations of the Canadian Department of Communications (DOC).

Le present appareil numerique n'emet pas de bruits radiolelectriques depassant les limites applicables aux appareils numeriques de la Classe A/B prescrites dans le reglement sur le brouillage radioelectrique edicte par le Ministere des Communications du Canada.

This system has been tested and found to comply with either the limits for a Class B digital device (without Model 180 Flow Sensor), or as a Class A digital device (with Model 180 Flow Sensor), pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment. This system generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable directions for use, it may cause harmful interference to radio communications. Operation of this system in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their own expense.

The authority to operate this system is conditioned by the requirement that no modifications will be made to the system unless the changes or modifications are expressly approved by Cardinal Health, Inc.

This Class A/B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.

Cet appareil numerique de la Classe A/B respecte toutes les exigences du Reglement sur le materiel brouilleur du Canada.

CAUTION

Any **changes or modifications** not expressly approved by the personnel responsible for compliance could void the user's authority to operate the system.

Tables: The SE Pump is intended for use in the electromagnetic environments specified in the following tables.

Table 1
Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
CISPR 11 RF Emissions	Group 1 Class A	The SE Pump is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following Caution is heeded:. **CAUTION** The SE Pump is intended for use under the supervision of healthcare professionals only. This is a CISPR 11 Class A when the Model 180 (Flow Sensor) accessory is used and a CISPR 11 Class B when the Model 180 is not used. In a domestic environment, this **system may cause radio interference**. Reorienting, relocating or shielding the system, or filtering the connection to the public mains network, are examples of steps that can be taken to reduce or eliminate interference.
CISPR 11 RF Emissions	Group 1 Class B	The SE Pump is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic Emissions	Class A	
IEC 61000-3-2 Voltage Fluctuations Flicker Emissions	Complies	

Table 2

Electromagnetic Immunity

Emissions Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
IEC 61000-4-2 Electrostatic Discharge (ESD)	±6 kV contact ±8 kV air	±8 kV contact ① ±15 kV air ①	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%. If connector testing exemption is used, following ESD sensitivity symbol appears adjacent to each connector. " - Do Not Touch"
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) ②	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Power Line Surge ②	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-8 Power Frequency Magnetic Field (50/60 Hz)	3 A/m	400 A/m 50 Hz ① 400 A/m 60 Hz ①	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 2 (Continued)
Electromagnetic Immunity

Emissions Test	IEC 60601-1-2 Test Level ③	Compliance Level ③	Electromagnetic Environment - Guidance
IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations ②	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If continued operation of the SE Pump is required during power mains interruptions, it is recommended that the SE Pump be powered from an uninterruptible power supply or a battery. The SE Pump does employ an internal short duration battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	

Table 3

Electromagnetic Immunity - Life Support Equipment

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level ①	Electromagnetic Environment - Guidance ④ ⑤
IEC 61000-4-6 Conducted RF IEC 61000-4-3 Radiated RF	3 Vrms 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	10 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to the SE Pump (including cables) than recommended separation distance calculated from equation applicable to frequency of transmitter. **Recommended Separation Distance** $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz - 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz - 2.5 GHz d = recommended separation distance in meters (m). ⑥ P = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range. ⑦ ⑧ Interference may occur in vicinity of equipment marked with following symbol:

Table 4 ④ ⑤ ⑥ ⑨

Recommended Separation Distances

Reduce the potential for electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SE Pump as recommended in this table, based on the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed in this table, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) based on the transmitter manufacturer.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance Based on Transmitter Frequency** (m)			
	150 kHz - 80 MHz Outside ISM Bands $d = \frac{3.5}{V_1}\sqrt{P}$	**150 kHz - 80 MHz In ISM Bands** $d = \frac{12}{V_2}\sqrt{P}$	**80 MHz - 800 MHz** $d = \frac{12}{E_1}\sqrt{P}$	**800 MHz - 2.5 GHz** $d = \frac{23}{E_1}\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.11	3.8	3.8	7.3
100	3.5	12	12	23

NOTES:

① Compliance levels raised by IEC 60601-2-24.

② Performed at the minimum and maximum rated input voltage.

③ U_T is the AC mains voltage prior to application of the test level.

④ At 80 MHz and 800 MHz, the higher frequency range applies.

⑤ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⑥ The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz, and in the frequency range 80 MHz - 2.5 GHz, are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

⑦ Field strengths from fixed transmitters [such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM/FM radio broadcast, TV broadcast] cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SE Pump is used exceeds the applicable RF compliance level, the SE Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SE Pump.

⑧ Over the frequency range 150 kHz - 80 MHz, field strengths should be less than [V_1] V/m.

⑨ The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz, and 40.66 - 40.70 MHz.

Compliance (Continued)

Standards

The SE Pump has been assessed and complies with the following standards:

IEC EN 60601–1 / BS 5724, including amendments A1 and A2; IEC EN 60601–2–24; CISPR 11, Group 1, Class A/B Emissions; IEC EN 60601–1–2, UL 60601-1, CAN/CSA No. 601.1-M90

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ALARIS®
MEDICAL SYSTEMS

Supplemental Information: Signature Edition® GOLD Infusion System, Model 180 Empty Container Detector (ECD)

This document provides supplemental information on emissions testing specifications located in Specifications section of Maintenance chapter of the Signature Edition® GOLD Infusion System Directions For Use.

NOTES: The Signature Edition® GOLD infusion system has been assessed and complies with the following Technical Standards: IEC EN 60601-1 including amendments A1 and A2; IEC EN 60601-1-2: 2002; IEC EN 60601-2-24; CISPR 11, Group 1. **Class A** requirements are met with use of ECD/flow sensor. **Class B** emissions requirements are met without use of ECD/flow sensor.

Class A Emission Statement:

Instrument used with an ECD/flow sensor, is suitable for use in all establishments other than domestic and those directly connected to public low-voltage power supply network supplying buildings used for domestic purposes. However, the Instrument may be used in domestic establishments with additional necessary (appropriate) measures.

Class B Emission Statement:

Instrument used without an ECD/flow sensor, is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network supplying buildings used for domestic purposes.

CAUTION

This Signature Edition® GOLD Infusion System is intended for use by Healthcare Professionals only. This is a CISPR 11, Class A Medical equipment/system when Model 180 accessory is used. In a domestic environment this equipment/system may cause radio interference, and may be necessary to take adequate mitigation measures, such as rearrange, relocate or shield the Signature Edition® System or filter the connection to public mains network.

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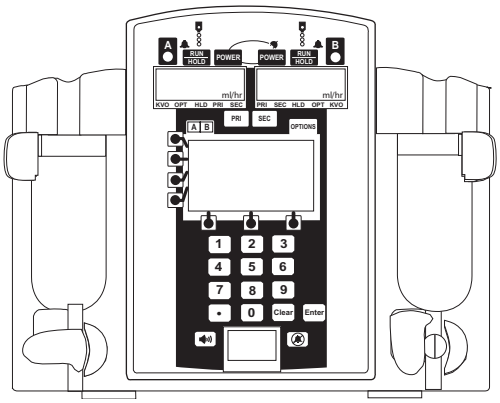
P/N 10010613

Directions for Use
SUPPLEMENT

Models 7130/7131 and 7230/7231

(With Guardrails® Safety Software or
Guardrails® Safety Software Compatible)



Signature Edition® GOLD Infusion System

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INTRODUCTION

About Directions for Use (DFU)

This Supplemental Directions for Use (DFU) provides information on current Standards for Electromagnetic Compatibility by IEC EN 60601-1-2:2002 a Collateral Standard for Electromagnetic Compatibility which the Signature Edition® GOLD Infusion System has been certified to.

Use this Supplement DFU in conjunction with Signature Edition® GOLD Infusion System DFU's. Also read and understand all instructions prior to using the Signature Edition® GOLD Infusion System.

Applicable CAN/CSA standards/requirements:

CAN/CSA No. 601.1-M90 - Safety of Medical Electrical Equipment. Part 1, General Requirements for Safety (including CSA 601.1 Supplement 1:1994 and CSA 601.1 Amendment 2: 1998).

UL Std No 60601 (1st Edition)-Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety

IEC EN 60601-2-24 (1st Edition)- Particular Requirements for the Safety of Infusion Pumps and Controllers.

Warnings and Cautions

For a complete listing of Warnings and Cautions, refer to the Signature Edition® GOLD Infusion System Directions for Use.

The following pages provide updates to existing information in the DFU sections:

Symbols and Terms

C SP® US

Canadian Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable Canadian and US electrical safety and performance standards (CSA C22.2, 601.1 and UL 60601-1).

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BASIC SYSTEM OPERATION

Warnings and Cautions

User Precautions

To ensure proper performance of the instrument and to reduce potential injury to the operator, observe the following precautions:

- Disconnect from main (AC) and battery power when performing maintenance.
- To disconnect from main (AC), unplug the power cord from the back of the instrument.
- Do not open the instrument case. There are no user-serviceable parts inside. The case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.
- The power cord must be connected to a properly grounded three-wire receptacle ("Hospital Grade").

RS-232 Computer Link and Nurse Call Options

- The protective cover over the RS-232 connector must remain in place when not in use.
- Only connect equipment to the RS-232 connector that complies with IEC EN 60601-1 or UL 1069 (approved medical or hospital signaling equipment).

User Precautions (Continued)

The following information is directed by the Standard IEC EN 60601-1-2:2002 for Medical Electrical Equipment - Part 1-2: General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility -Requirements and Tests. These provide certain Warnings and Cautions text that must be included into the Directions for Use.

WARNINGS

- Use of any accessories or cables with the Signature Edition® Infusion System other than those specified may result in increased emissions or decreased immunity of the instrument.
- The instrument should not be used adjacent to or stacked with other equipment, if adjacent or stacked use is necessary, the instrument should be observed to verify normal operation in the configuration in which it will be used.
- The Signature Edition® Infusion System is intended for use under the supervision of healthcare professionals only. This instrument may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the instrument or shielding the location.
- Only connect equipment to the RS-232 connector that complies with IEC EN 60601-1 or UL 1069 (approved medical or hospital signaling equipment).

CAUTIONS

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed, placed into service and used according to the EMC information provided.
- Portable and Mobile RF communications can affect Medical Electrical Equipment.

Specifications

Power Requirements: 100-240 V~, 50/60 HZ (72 VA max), 3-wire grounded system
Class 1 with Internal Power Source

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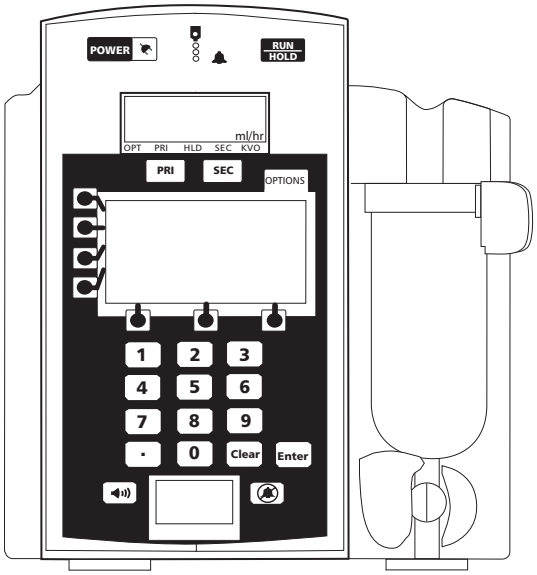
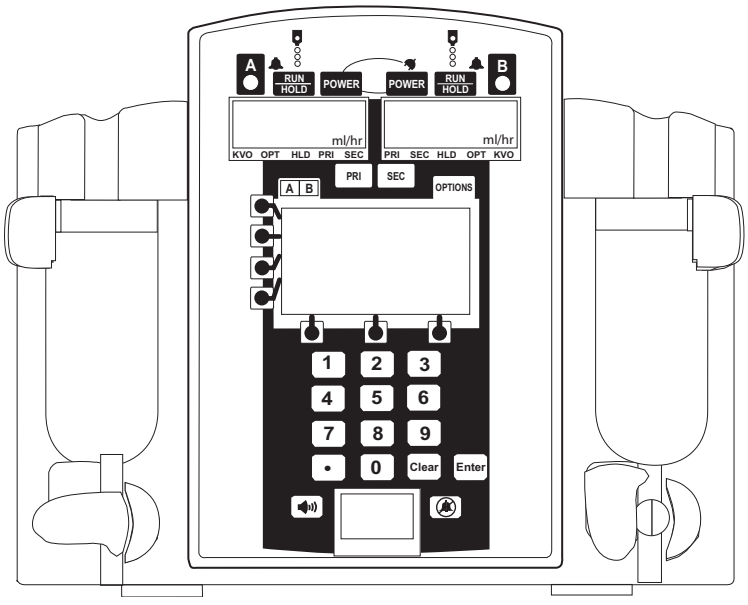
Directions for Use Supplement

Alaris® SE Pump

Models 71XX, 72XX

December 2006





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Introduction

About This Document

This supplemental Directions for Use (DFU) provides an update to the Alerts information found in the "Troubleshooting and Maintenance" chapter in the applicable DFU for each Alaris® SE single and SE dual channel pump (formerly known as the Signature Edition® Infusion System).

WARNING

Before using the Alaris® SE pump, **read all instructions** in the applicable DFU.

Alert

The following Alert is in addition to those provided in the applicable Alaris® SE pump DFU.

Alert	Meaning	Response
CHECK ENTRY	Key press unclear.	press Clear key to continue

Important Notes

- **Listen to Audible Tones.**

- **Verify Screen Displays**

  Verify prescribed therapy on display screen prior to starting or restarting an infusion.

- **Observe Flow Rate**

  Observe the IV tubing drip chamber to verify expected flow.

WARNING

Verify all programming parameters on the display screen are correct prior to initiating RUN/HOLD.

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